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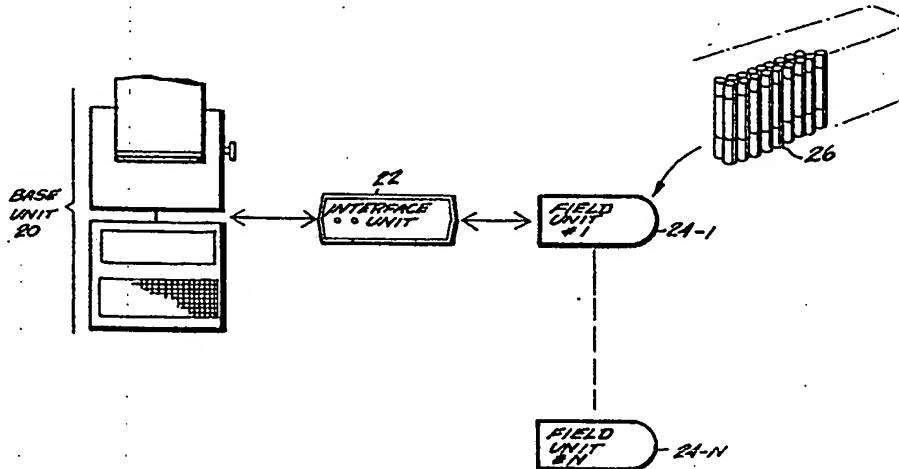
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(54) Title: CONTROLLED DISPENSING DEVICE



(57) Abstract:

The invention relates generally to the art of controlled dispensing and compliance monitoring. Prior art devices relating to medication compliance monitoring lack the necessary control mechanisms to administer complex drug regimens to patients. The present invention overcomes the deficiencies by providing a controllable dispensing device for use by a drug therapist for the unsupervised administration to a patient of a drug therapy regimen. A field unit (24) is loaded with a plurality of medication containers (52) in a predetermined sequence. Along with the medication, a program of dosing times is stored in electronic memory (102) of the field unit. This program is defined using a computerized base unit (20) and is transferred to the field unit via an interface (22) between the base and the field units. The field unit includes a display (204) and alarm (208) for alerting the patient as to the times for dispensing and administering the medications in the containers. The field unit permits dispensing of containers only in accordance with the predefined dispensing. Later, the field unit can be debriefed by the base unit via the interface and the base unit prepares a report of medication compliance for the drug therapist.

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CONTROLLED DISPENSING DEVICEBACKGROUND OF THE INVENTIONField Of The Invention

This invention relates generally to the art of controlled dispensing and compliance monitoring. It has particular application to the art of unsupervised drug dispensing to a patient although the principles of the invention apply to controllable dispensers of any types of material.

The presently preferred embodiment of the invention provides a controlled medication dispenser. The dispenser can be preprogrammed by a drug therapist using a base unit (specially programmed computer) to which the dispenser is temporarily coupled, to permit a patient access to drugs stored in a portable field unit only in accordance with predetermined criteria, such as for example at particular times. A digital display on the dispenser specifies the next dosing time and will instruct the patient on proper make-up doses in the event of missed doses. The portable field unit records actual times of medication dispensing and can easily be debriefed by the base unit (computer) which then prepares a medication compliance report for the drug therapist.

Background Of The Invention

"Controlled dispensing" refers to the concept of permitting a user to dispense some item according to a predetermined schedule or set of rules, rather than permitting unrestrained access.

A significant application of the art of controlled dispensing relates to drug dispensing.

"Compliance monitoring" refers to the concept of recording a user's actual dispensing activity compared to a previously prescribed regimen. A significant application to the art of compliance monitoring also relates to drug therapy.

5 As drug research and therapy become more and more sophisticated, drug researchers and therapists have an increasing need to administer complex drug regimens to patients; to restrict access to medications in some instances; and to  
10 evaluate the patients' compliance with those drug regimens.

15 The most accurate way of administering a drug regimen and measuring compliance of a patient or test subject is direct supervision of each dose of medication. The manpower required for this type of drug administration is extraordinary and usually requires hospitalization. The alternative of prescribing a drug regimen and leaving it completely to the patient to follow and report back usually  
20 results in poor compliance and inaccurate reports.

25 Controlled drug dispensers and compliance monitoring equipment provide a middle ground between direct supervision and no supervision so that relatively dangerous drugs can be administered without direct supervision and clinical drug studies can be carried out with relatively high reliability.

30 As the U.S. Department of Commerce National Technical Information Service Publication PB-278 973 entitled "Possible Designs of Medication Monitors", prepared at the National Jewish Hospital and Research Center, Denver, Colorado, for the American Lung Association (April 1978) points out, the genesis of the medication compliance monitor goes back to May 1962. This early concept was for a

medication monitor utilizing radioactive material and photographic film to determine when patients removed medication from a medication dispenser.

5 Since then there have been several publications on different devices utilizing the same principle, as well as field trials. Since the original publication, the interest in the field of patient compliance with drug regimens grew enormously.

"The Unrealized Potential of The Medication 10 Compliance Monitor" was discussed by Thomas S. Moulding, M.D., at the National Jewish Hospital in a February, 1979 commentary appearing in Volume 25, November 2, of Clinical Pharmacology and Therapeutics. That commentary provides some insight 15 to the historical development of the art of medication compliance monitoring. This Moulding commentary discusses an early version of a radiographic-type compliance monitor. As medication compliance monitoring further developed, various 20 arrangements appeared in the literature and marketplace. Moulding describes a radiographic compliance monitor capable of showing dosing patterns. Each container holds a full daily dose of medication. However there is not provided any 25 alerting features to help the patient to remember to take dosages. Processing and interpreting the compliance record are awkward. Potential hazards are associated with the use of a radioactive source. No control mechanisms are used -- Access is 30 not controlled nor is the number of dosages taken at one time.

Moulding anticipates the use of strip packaging and microprocessors for improving compliance monitors' design but no practical details

are given on how to accomplish these design improvements. It does not appreciate the utility of a device capable of delivering multiple medications in complex regimen. The commentary does not teach how to build a reliable and tamper-proof dispensing mechanism; a successful strategy for field, 5 interface, and base unit electronics and software is not given.

Lederle Laboratories (American Cyanamid Company) developed a digital module for the cap of a medicine bottle for reminding the patient when he 10 last took his medication. This "reminder" cap was intended to help people to take medication at the proper time. However, such an arrangement has certain fundamental inadequacies: The clock does not indicate when the next dosage is due. The 15 patient must still remember the proper dosage schedule. There is no alarm to get the patient's attention when the next dosage is due. The cap has no memory to show the therapist when dosages were taken. There is no control over when the bottle cap 20 is opened or the number of dosages taken after the cap is removed. Also, multiple caps are needed for multiple drug therapies; and the patient is not guided as to how much of each drug is to be taken.

A "Med Tymer" medicine bottle cap was 25 developed by Boston Medical Research, Inc. It includes preprogrammed light and sound alarms that announce when the next dosage is due. 1/day to 4/day schedules are available. However, it also has several functional limitations. Programs are in 30 firmware and are not adjustable. Thus, there is no flexibility of dosing times for a given daily frequency. The cap has a limited lifespan (12 months) and is not reusable or reprogrammable. It

is not approved for liquid medications. It has no memory for later reporting of compliance. There is no control over when the cap is opened or the number of dosages taken after the cap is removed. Multiple caps are needed for multiple drug therapies; and the patient is not guided as to how much to take of each medication.

In an article entitled "Medication Monitor for Ophthalmology" by Yee et al appearing at page 774 of the American Journal of Ophthalmology, there is described a medication monitor wherein dosing times are recorded in memory for later reporting of compliance. Its functional limits are as follows. There are no alerting features such as an alarm, or clock displays, etc. The electronics provide only a limited memory, i.e. there is no microprocessor to provide alarm and control functions and the limited memory results in limited dosing record resolution. It is only possible to achieve one hour resolution of dosage taken times; and multiple doses within any given hour cannot be recognized. There is no control over when the cap is opened or the number of dosages taken after the cap is removed. Multiple units are needed for multiple drug therapies; and the patient is not guided as to how much to take of each medication.

A sample of the patent literature in this art includes:

- U.S. Pat. 3,369,697, Glucksman et al, Feb. 20, 1968
- U.S. Pat. 3,968,900, Stanbuk, July 13, 1976
- 30 U.S. Pat. 4,223,801, Carlson, Sept. 23, 1980
- U.S. Pat. 4,293,845, Villa-Real, Oct. 6, 1981

SUMMARY OF THE INVENTION

The present invention provides a controllable dispenser having significantly improved operational features over known dispensers.

The dispenser's operation is based upon a packaging concept that places containers along a flexible strip in a predetermined order. The containers may be attached to the strip in various ways. For example, the containers may be integral to the strip material itself, or they could be placed in pockets or sleeves formed in the strip material. Strip materials are typically plastic films that have been heat sealed to form the container holding pockets or adhesive backed fiber tapes sandwiched around non-sticking sleeves, although many other combinations of materials could provide the same effect. More rigid materials could be used for strip construction, but much more efficient container storage is possible if the strip material is flexible enough to allow the containers to be positioned such that neighboring containers are touching one another. Strip flexibility is also beneficial in insuring smooth movement of the strip around turns in the storage volume. Strip materials should not be so weak that tensile forces occurring during the dispensing operation stretch the strip and alter important container spacing intervals.

Container attachment points are spaced at intervals along the strip that correspond to engagement location spacings on the dispensing mechanism. These strip and dispensing mechanism spacings permit a rack and pinion type of dispensing operation. Although almost any spacing

interval may be chosen, minimal spacing limitations will arise for given container packing arrangements. For hexagonal closest packing arrangements (as shown in Figure 4), the minimal spacing between containers is approximately one-third the container circumference. Using the nomenclature of Figure 3,  $S_{min} \geq c/3$ . Parallel packing arrangements (as shown in Figure 5) require a spacing length of at least one container diameter,  $S_{min} \geq d$ .

Various container shapes and sizes may be accommodated by the dispenser's structural arrangement. Depending upon storage volume design and the shapes of parts of the dispensing mechanism, containers having square, semicircular, or other cross-sections may be acceptable. However, circular cylinders are particularly useful containers, having a shape that packs efficiently for storage, moves freely through the storage volume passageways without jamming, and is reliably engaged by the dispensing mechanism. Containers may be made of any rigid or semi-rigid material. Although more flexible container walls can aid the containers in passage through the storage volume and the dispensing mechanism, too flexible materials might prevent the container from maintaining the approximate shape required for proper engagement by the dispensing mechanism.

Varying container volumes are accommodated by merely changing the length of the container. Since the container cross-section remains the same, a dispensing device design is then possible that accommodates various container volumes by merely changing the height of the storage volume and ejector mechanism. No changes

to the design of the dispensing mechanisms are necessary.

The packaging system of this invention offers several advantages over previously known arrangements. The dispenser is useful for dispensing various kinds of materials, but it is particularly useful for medication dispensing. A wide variety of containers having various diameter to length ratios may be used. By using a container that is leakproof and has a relatively wide opening, a single dispensing device may be used in several different applications. For example, the leakproof 5cc vials used in the medication dispenser/monitor/controller implementation of this design will accommodate almost any medication presentation, including: liquids, suspensions, salves, tablets, capsules, devices, and even multiple compatible substances within a single vial. Further flexibility is provided in that other container volumes can be accommodated by merely changing the length of a container with a given cross section. Only the height of the storage base and ejector pinion need then be changed. Thus, the design and size of the device's dispensing module (containing the electronics and dispensing mechanisms) and the spacing intervals of the flexible strip do not change. One dispensing module may be used with several storage bases and ejector pinions to provide a wide range of container capacities and optimized (minimal volume) package sizes.

Another significant feature relates to individual packaging. The proper amount of the substance to be dispensed is placed in individual containers instead of allowing the user access to

a bulk supply and relying upon him or her to dispense the proper amount. The amount of the substance to be dispensed is precisely metered into the individual containers by the pharmacist/therapist and can be double checked 5 before the device is handed to the user. The same metering precision and reliability over many dispensing operations is not likely to occur when the user must do the measuring or a mechanical device must repeatedly measure and dispense from a 10 bulk supply.

Using individual containers helps prevent contamination and cleaning problems and thereby enhances the economics of such a reusable system. The dispensing device can be used for 15 dispensing one type of substance and, upon completion of the first dispensing program, be immediately reloaded with vials containing a different substance with very little chance of cross-contamination and no substantial cleaning 20 requirements. Bulk or even compartmentalized storage volumes would need extensive cleaning before reuse.

Complete control over dispensing sequencing is provided. The capability of varying 25 the amount and types of substances within each container and organizing these varying contents into a predetermined sequence is a primary feature of the invention. Using the medication dispenser/monitor/controller example, the device 30 could be loaded with vials containing various combinations of drugs in the proper sequence such that a patient on multiple regimens will receive the proper selection of medications according to

the prescribed schedules, and without the patient having to remember any dosing details.

The sequencing feature may also be used to deliver increasing or decreasing amounts of one or more substances over the dispensing period.

5 Thus, a physician using the medication dispenser/monitor/controller to administer medications can taper dosage levels and thereby deliver more effective therapeutic levels while simultaneously minimizing side effects in a manner 10 simultaneously minimizing side effects in a manner not possible using level doses.

The dispenser according to the invention is tolerant of any positional orientation. Unlike gravity feed devices, the dispensing device according to the present invention will operate 15 properly in any orientation. The container strip maintains container sequencing and proper spacing regardless of position. Some storage volume characteristics, described later, also help prevent undesirable container movement and thereby 20 contribute to the device's orientation tolerance.

The packaging of containers along a flexible strip forms a flexible rack-like device that, in combination with the pinion-like dispensing mechanism described below, permits the 25 construction of a very compact and reliable dispensing device.

The primary dispensing mechanism includes an ejector element mounted for rotation about its longitudinal axis and having container conforming 30 depressions positioned around its periphery. The ejector acts as a pinion gear that drives a flexible rack, the container strip. When the ejector is rotated, one container is moved from a ready position and out of the dispenser while,

simultaneously, the next container to be dispensed is engaged by a mating ejector depression and moved into the ready position.

Thus, the pinion, the ejector element having depressions that form gear-like teeth, is 5 fixed, and the rack, a flexible strip with attached containers acting as the mating gear teeth, is moved out of the device by pinion rotation. This design offers many advantages:

10 The first of these advantages is reliability. Using the containers as the 'teeth' on the rack provides inherently more reliable pinion engagement than a conventional flexible strip with rows of small holes used to engage pins on the pinion (as in camera film for instance).  
15 Accurate engagement location spacing is essential to jam free operation in both cases. However, the container as sprocket design has only one critical spacing per dispensing operation, whereas for a multiple hole rack, several accurate hole to hole intervals are needed for the same single dispensing operation. Strip manufacture is also simplified by using the containers as sprockets. Punching the multitude of precisely positioned small holes is not required.

20 25 The mechanism operates simply. A 1/4 turn of the ejector pinion is all that is required to accomplish a dispensing operation. The container is then outside the device where it can be slid out of its sleeve for use and the empty strip is torn off across the opening edge.

30 As discussed above, the same dispensing mechanisms may be used to dispense various volume containers merely by changing the length of the ejector pinion to correspond with the associated

container length. Like the container strip, the dispensing mechanism may be operated from any position.

Completed dispensing operations are signalled to a microprocessor by means of lever switches activated by spring loaded actuators riding cams on the shaft used to drive the ejector pinion. The mechanism is designed to activate the signalling switches when the user has completed the 1/4 turn drive shaft rotation. False signals are prevented by using two switches that are alternately, mechanically activated by cams 90° apart and by alternately arming the switches electrically by means of microprocessor output ports. Thus, as soon as a particular switch is activated mechanically, it is deactivated electrically immediately after the signal is received so that further minor motion of the ejector driveshaft is not improperly interpreted as another completed dispensing operation.

Simultaneously, the other switch is electrically armed so that it will signal the microprocessor upon the next 1/4 turn rotation and ensuing mechanical activation.

The flexible rack and pinion mechanism described above is the basis for a superior dispensing system having the advantages discussed above. However, in situations requiring the utmost reliability and control, such as the medication dispenser/monitor/controller application, further mechanical and electromechanical features can greatly enhance reliability. The features listed below may be used separately or in various combinations as

required to insure reliable operation in a particular dispensing situation.

The first group of features relates to the housing. The dispensing device components may be housed in two sections. The lower section, the 5 storage base provides a storage volume for the container strip and retains the ejector pinion. The upper section, the dispensing module 46, houses the electronics and all the dispensing mechanisms other than the ejector pinion 34. Both 15 housings may be of one piece, fastenerless construction. The two housing parts are held together by a cabinet lock mounted in the dispensing module, and having a key operated cam that engages slotted extensions of a partition 30 20 in the storage base. This construction provides several beneficial features.

The tongue and groove mating of the upper and lower housings allows a simple one point locking design having a tamper-resistant joint. 25 Since the user is not given the key to the cabinet lock, there is no easy access to the contents of the dispensing device other than through proper manipulation of the ejector mechanism. Both the storage base and dispensing module are free of 30 external fasteners so that tampering is discouraged and difficult to hide if attempted. The opening in the storage base where containers are ejected is protected against intrusion by the design of the ejector pinion. The sprockets of 35 the ejector pinion are such that they form a close fitting barrier with the storage base partition and thereby prevent viewing of and access to the next container to be dispensed.

There are no unsealed openings in the top of the device through which spilled fluids could reach the electronics and mechanisms. The tongue and groove method of joining top and bottom housings further protects against spills. Since 5 all the electronics and all the dispensing mechanisms except the ejector pinion are mounted in the top housing, any leaking containers are not likely to contaminate those elevated regions. Further protection against leakage contamination 15 can be easily attained by sealing a cover plate over the bottom of the dispensing module, thereby protecting all mechanisms and electronics with one simple cover. A coating provided over the electronics can provide additional protection.

Smooth, jamproof, container strip movement is a feature of the storage base 20 design. As shown in Figure 4, the storage base outer wall and inner partition form a generally U-shaped storage volume in which containers are packed both inside and outside the partition. 25 This design provides exceptionally efficient (compact) container storage while simultaneously providing passageways through which the container strip can move smoothly without jamming.

By keeping all passageways a little less than two container diameters "d" (See Figure 3) in width, containers cannot get past one another and out of sequence. Thus, impact forces cannot rearrange container sequencing and cause 30 containers later in the sequence to engage the ejector pinion ahead of earlier containers and jam the mechanism. Because a minimum passageway width of 1.87 diameters is needed to allow double row, closest packing as is desired in some areas, the 35

passageway widths in those regions are typically kept between 1.87 and slightly less than two (2) diameters.

The U-shaped design allows for smooth container strip movement since there are only two partition turns, at a maximum, for the containers to negotiate. The radii of the turns are large enough, compared to the inter-container spacing, so that most contact with the partition is by the containers and not the spacing intervals. Because the containers only have line contact with the partition wall, very little frictional force is generated and the containers move smoothly around the turns. Tighter radii would allow more strip contact with the partition wall and produce larger drag forces that might bind strip movement.

5 Circular storage volumes, having capacities as shown, are not preferred because they have housing proportions that are hard to hold in one hand. Similarly, even though longer, rectangular designs 15 can have fewer turns, the extended housing length can make portable units awkward to carry.

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The two part housing design is also beneficial to the user who may want the capability of dispensing several different capacity containers with a minimum equipment investment. Since all electronics and mechanisms other than the ejector pinion are contained in the top half dispensing module, container capacity can be changed merely by using a container of the appropriate length to give the volume desired, and by using a storage base and ejector pinion of corresponding length. No change in dispensing module size or design is required. Thus, one dispensing module can be used with several

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different height storage bases, ejector pinions and containers to produce a broad capability dispensing system.

5 There are several mechanisms associated with control of ejector pinion motion that help insure reliable operation.

10 A pin 92 located in the storage base (See Figure 22), under a groove in the ejector pinion, prevents further ejector rotation until the dispensed container is removed. This pin prevents inadvertent, or intentional, attempted insertion of containers back into the unit which could jam the ejector mechanism.

15 The two alternately acting ejector switch actuators described above have a second function. The depressions in the drive shaft that engage the spring loaded actuators are shaped so that the drive shaft cannot be turned in the reverse direction once an actuator has seated. Thus, the drive shaft can be turned backwards at 20 most something less than one-quarter turn and not at all once the fully dispensed position is reached. By preventing reverse ejector rotation, containers are prevented from being intentionally or inadvertently pushed back into the storage 25 volume and thereby possibly jamming the dispensing mechanism, or disengaging the ejector pinion.

Pins are arranged in the top of the 30 ejector pinion such that they extend into the dispensing module. A notched locking wheel 86 is positioned in the top housing so that its circumference will prevent ejector pinion rotation unless the notch is so aligned as to allow the adjacent ejector pinion pin to rotate forward. The notch is so designed that as the ejector

pinion rotates forward a pin engages the notch well and forces the locking wheel to rotate before disengaging the notch. Once the locking wheel is turned, the notch is no longer in a position such that the next ejector pin can move forward, 5 and the ejector pinion is thereby locked.

Thus, ejector pinion locking occurs automatically and mechanically each time a container is dispensed. This auto-lock feature prevents the operator from inadvertently 15 dispensing too many containers by rotating the ejector pinion more than 90 degrees. Being mechanical and automatic, the mechanism requires no computer logic or power to perform this function. This locking design also permits a 20 simple, but effective, computer controlled unlocking feature that can be used to better insure operator conformance to a predetermined dispensing schedule.

Where restricted access to the containers 25 is not important, a simple mechanical linkage can allow the operator to manually reset the locking wheel so that the notch is aligned to permit another dispensing operation. In other situations, where precise control over the 30 dispensing operation is desired, a solenoid 212 controlled by the dispensing device's microprocessor can be easily put in control of the locking wheel. When an electrical pulse is supplied to the solenoid, it rotates the locking 35 wheel 86 in the reverse direction (approximately 45° in this example) so that the notch 90 is moved into the unlocked position.

Although a linear acting solenoid with linkages can be used to reverse rotate the locking

wheel into its unlocked position, no linkage is necessary if a rotary acting solenoid is used and a simpler, more reliable design results. The choice of a rotary solenoid over a linear solenoid also greatly increases the impact resistance of 5 the dispensing mechanism. Linear acceleration/deceleration forces (due to impacts, for instance) in the direction of the longitudinal axis of the plunger of a linear solenoid could cause the locking mechanism to lock or unlock when 10 not intended. Since linear forces produce balanced and opposed forces when acting on a rotational mass, impact forces do not tend to cause inadvertent armature motion when a rotary solenoid and locking disc are used.

15 Further means of insuring that lock/unlock positions of the locking wheel are retained can be provided through the use of latching forces. Latching mechanisms increase the force required to move the locking wheel out of 20 either one of its bistable positions. One form of the latching mechanism utilizes three magnets: one on the locking wheel, and two others mounted such that they are adjacent the locking wheel 25 magnet and providing attractive (latching) forces when the wheel is in its lock and unlock positions. Although there are many other possible latching designs (such as spring loaded rockers), the described magnetic system uses just three simple parts that can be easily adjusted to 30 provide the optimum latching forces. By adjusting the magnets' residual field strengths during magnetization, the resultant latching forces may be made just sufficient to prevent accidental motion of the locking wheel with no excess force

that would require the use of a larger and higher power consuming solenoid. Since a rotary solenoid greatly reduces the latching forces required because of its inherent stability under linear forces, the torque requirements of the design are 5 minimal.

A lever switch ("status" switch) adjacent a cam on the locking wheel is used to signal to the microprocessor the status of the locking/unlocking mechanism. This provides a 10 check to see that the locking wheel has been able to respond properly to commands from the microprocessor. If, for instance, the user has prevented locking wheel reset by applying restraining forces through attempted drive shaft 15 rotation during the solenoid pulse, this switch will alert the microprocessor to the need for sending additional pulses to the solenoid until the unlocking operation has been successfully completed.

20 The dispensing device described above can certainly perform all its functions, with all the stated benefits, from a fixed location using externally supplied power. However, the structure 25 has been particularly optimized for portable operation using self contained batteries. Portability is especially beneficial to the medication dispenser/monitor/controller application where small size and battery operation are essential.

30 Several features contribute to efficient utilization of space within the unit:

a. Hexagonal, closest packing - much of the storage volume is configured for double row, closest packed storage which results in maximum

container densities. The flexibility of the container strip allows the containers to be pushed next to one another to accomplish closest packing.

5 b. Optimum partition design - the U-shaped partition folds the container strip into a compact area while providing large radius turns that help insure smooth strip movement. Virtually the entire area inside and outside the partition may be filled with containers. Single row designs, such as one using a spiral partition in a 10 round enclosure, require more extensive partitions that waste space and have more turns that increase the undesired drag forces on the strip as it is advanced. On the other hand, use of too few partitions risks the possibility that containers 15 will not advance in the proper order and thereby jam the dispensing mechanism.

The U-shaped design also affords the most easily grasped and carried device proportions. Round devices having comparable capacities have 20 diameters that are too large to comfortably grasp without a handle. More rectangular designs of similar capacity have a length dimension that becomes more awkward to accommodate during transport and storage.

25 c. Minimum wall thickness - The outer wall and partition thicknesses have been minimized to save volume and weight. Using extensions of the storage base partition, instead of a base mounted post, to engage the upper housing cabinet 30 lock maximizes the space available for container storage.

d. Housing adaptability - The placement of all electronics and dispensing mechanisms in the top portion of the device allows the height of

the separate storage base to be adjusted to exactly fit the height of the containers.

5 e. VLSI circuits - Very large scale integrated circuits are used, each of which perform the function of several circuits in just one package, thereby saving large circuit board areas and reducing unit weight.

10 f. Plastic construction - Almost all housing and support structures, as well as several of the dispensing mechanisms, may be suitably constructed of plastic materials, thereby lessening the weight that must be carried.

15 g. Software features - By implementing in software several functions normally implemented in hardware, valuable space and weight are saved. The usual UART (Universal Asynchronous Receiver/Transmitter) and parallel interface hardware elements have been implemented in software. Serial communications are used to simplify the hardware necessary for communications 20 with the Base Unit. The level shifting circuitry needed by the communications link has been moved out of the dispensing device and into the Interface Unit to save more dispensing device space.

25 So that the dispensing device could be used in applications such as the medication dispenser/monitor/controller where the battery power supply must provide up to 60 days or more of continuous operation, many power saving features 30 have been implemented.

a. CMOS circuitry - All integrated circuits are of Complementary Metal Oxide Silicon construction for lowest possible current draw.

b. 'WAIT' mode - The use of a microprocessor having a low power standby operating mode and software that places the MPU in that power saving mode for more than 98% of its 5 operating period is the major power saving feature.

c. Piezoalarm - The reminder alarm function is implemented with a piezoelectric element that uses only a few milliamperes of 15 current. Further power savings result by only pulsing the alarm for a fraction of every minute.

d. LCD - A liquid crystal display is used as the visual dispensing reminder because it uses only microamperes of current.

e. Mechanical auto-lock - The auto-lock feature requires no electrical power, the motive force being supplied by the dispenser operator 20 while advancing the ejector pinion drive shaft.

f. Manual ejector drive - Although the ejector pinion could be motor driven to ease the dispensing operation for the fixed location user where external power is readily available, the 25 manual drive design permits portable operation where the large amount of power required for an electric drive is not available.

g. Rotary solenoid - As described above, 30 a rotary solenoid requires less latching forces and therefore less starting torque (power) than a linear solenoid design. Rotary solenoids also provide superior starting torque for a given 35 current and size. The unlock mechanism is designed so that the unlock solenoid need merely rotate a lightweight locking wheel. No linkage forces have to be overcome that would require the 40 use of a bulkier, higher current draw solenoid.

Further, the solenoid driving software routine sends only a 50 msec pulse of power to the solenoid, limiting power used to the minimum needed to accomplish reliable unlock operation. Only pulses of power need be sent to the unlock 5 solenoid since the mechanism is latched once it reaches the unlock position and no further power is needed to maintain the proper position.

h. VLSI circuitry - The use of highly integrated circuits reduces power consumption 10 compared to discrete devices performing the same functions.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a block diagram of the medication dispenser and compliance monitor system 15 according to the present invention;

FIGURE 2 is an exploded, partially cut-away view of a field unit 24;

FIGURE 3 is a schematic representation of containers on a strip showing dimensions and 20 spacings;

FIGURE 4 is a top view of the storage base portion of the Field Unit showing containers to be dispensed stored therein;

FIGURE 5 is a schematic representation of 25 an alternative container storage arrangement;

FIGURE 6 is a schematic representation of an integral strip and storage container;

FIGURE 7 shows a strip arrangement including two portions heat sealed to one another;

FIGURE 8 shows a two portion strip 30 50 with a container held between the two strip portions;

FIGURE 9 shows a container with a separate plug cap;

FIGURES 10-12 are schematic diagrams showing a dispensing operation;

FIGURES 13 and 14 are side views of a 5 portion of the dispenser module showing how a dispensing operation is signalled;

FIGURES 15 and 16 are schematic views further illustrating how a dispensing operation is signalled;

10 FIGURES 17-19 are schematic illustrations demonstrating the automatic locking mechanism;

FIGURE 20 is a side view showing the operation of the locking wheel by the rotary solenoid;

15 FIGURE 21 is a top view of ejector pinion 34 showing the position of the container stop pin;

FIGURE 22 is a cross sectional side view showing the position of the container stop pin;

20 FIGURE 23 is a cross section view of the assembled Field Unit;

FIGURE 24 is a view looking up at the dispensing module portion of the field unit;

25 FIGURES 25 a and b are a schematic diagram of the electronic subsystem of the field unit;

FIGURE 26 is a flow chart of the software controlling the operations of the field unit;

FIGURE 27 is a schematic diagram of the interface unit 22;

30 FIGURE 28 is a block diagram of base unit 20;

FIGURE 29 is a flow chart of the base unit loading routine software for loading a field unit;

FIGURE 30 is a flow chart of the base unit unloading routine software for debriefing a field unit after it has dispensed some or all of its containers;

5 Appendix I is a detailed listing of the software controlling the field unit;

Appendix II is a detailed program listing of the loading routine shown in flow chart form in figure 29; and

10 Appendix III is a detailed program listing of the debriefing routine shown in flow chart form in figure 30.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

##### System Overview

Referring first to FIGURE 1, there is shown a block diagram of the overall system concept of the present invention. The system includes a single base unit 20, a single interface unit 22 and a plurality of field units 24-1 . . . 24-N. A drug therapist or researcher can program 15 many field units 24 (one at a time), give them to different patients or subjects and later collect and debrief them and prepare compliance reports.

To prepare a field unit 24 for distribution to a patient or test subject, a 20 medication package, such as package 26, is first loaded into field unit 24. The field unit is then electrically connected with interface unit 22 and a programmed drug regimen, defined by the therapist by interacting with base unit 20, is 25 loaded via interface 22 into the field unit. The drug therapist defines the drug regimen by using 30

the "LOAD-M" software (set forth in Appendix II) with base unit 20 to configure the field unit 24.

5 The loaded field unit 24 is given to the patient, who dispenses medication in accordance with the schedule loaded into it using the "LOAD-M" software. The dispensing operation is governed by the software stored in field unit 24 and listed in Appendix I. This field unit software provides dosing time prompts, controls the dispensing mechanism, and stores the actual times and dates 10 of dispensing.

15 After the drug regimen is completed, field unit 24 is returned to the therapist where it is again connected to base unit 20 via interface 22. The field unit is then debriefed according to the software listed in Appendix III and the base unit prepares a report to the therapist as to exact times of dispensing and any departures from the desired schedule.

#### Field Unit Mechanics

20 Referring to FIGURES 2-24 there are shown the mechanical details of a field unit 24.

25 Referring first to Figure 2, there is shown an exploded view of field unit 24. Field unit 24 includes a storage base 28 constituting a portion of the housing of the field unit. Inside of storage base 28, there is fitted a storage base inner partition 30 which, together with an outer wall 32 of the storage base defines a passage way within which a dispensing package 26 can be stored 30 and from which individual containers can be dispensed. The dispensing action is carried out by the rotation of an ejector pinion 34 which is manually rotated by the user by manipulation of a

knob 36, during times when the field unit is "unlocked" in accordance with a predetermined dispensing schedule stored in it. The unlocking mechanism operates under microprocessor control as will be described later in further detail.

- 5        Inner partition 30 includes two slotted extensions 38 and 40 which pass through a hole 42 in a plate 44 and ultimately engage with a cam lock (not shown in Figure 2) in a dispensing module portion 46 of Field Unit 24. Dispensing
- 10      module portion 46 includes various mechanical elements, electronic subsystem, display, alarm, etc. A slot 48 on the upper surface of dispensing module portion 46 accommodates a key for a cam lock.
- 15      Dispensing package 26 includes a strip 50 holding a plurality of individual containers 52, each having its own cap 54. Package 26 is fitted into the passageway defined by outer wall 32 and inner partition 30 of storage base 28 according to
- 20      a predetermined sequence. Each time a container 52 is to be dispensed, ejector pinion 34 is rotated so as to engage a single container 52 and push it through an opening 56 in outer wall 32 of storage base 28. Ejector pinion 34 is rotated by
- 25      the user by means of rotating drive shaft Knob 36.

- 30      Ejector pinion 34 includes four locking pins 58 which cooperate with an unlocking arrangement for controlling when ejector pinion 34 can be rotated in accordance with the predetermined schedule. Ejector pinion 34 includes four concave portions 60 for accommodating the shape of individual containers 52 so that a container fits within concave portion 60 and is conveyed by rotation of the ejector pinion.

Referring now to Figure 3, there is shown a schematic representation of a portion of a medication package 26 including strip 50 and two (2) containers 52. Each container has a 5 circumference "c" and a diameter "d". There is a space "s" separating two adjacent containers 52.

Referring now to Figure 4, there is shown a top view of storage base 28 of field unit 24 with the dispensing module portion 46 removed. 10 This figure shows a plurality of containers 52 packed within the passage way defined by inner partition 30 and outer wall 32. The arrangement of containers 52 shown in this Figure where the passageway is widest represents what is known as 15 "hexagonal closest packaging" which allows the maximum number of containers 52 to be stored within the passage way volume. The minimum inter-container strip spacing required for closest packing is shown as the length Smin. The numbers shown inside each of containers 52 represent the 20 sequence of dispensing of the individual containers. First, container #1 is dispensed, then container #2 is dispensed, etc. Each dispensing operation corresponds to a 1/4 turn of 25 ejector pinion 34. As individual containers 52 are dispensed, strip 50 is pulled and the undispensed containers advance through the passage way as necessary toward ejector pinion 34.

Referring now to Figure 5, there is shown 30 an alternative, but not preferred, packaging arrangement of containers 52 known as "parallel row packaging". The numbers inside each of containers 52 represent the sequence of dispensing of the containers. The minimum inter-container

strip spacing required for parallel row packing is shown as the length  $S_{min}$ .

Containers 52 can either be formed integrally with strip 50 as shown in Figure 6 or the containers can be fitted within spaces formed in strip 50 to accommodate the containers. As shown in Figure 7, strip 50 can be formed from two separate and distinct strips of material 62 and 64 which can be sealed adjacent to container areas. The individual containers 52 can then be inserted into the space defined by the two strips of material.

Referring to Figure 8, there is shown such an arrangement including strips of material 62 and 64 with a container 52 inserted therein.

Referring now to Figure 9, there is shown a more detailed view of a portion of medication package 26. Each container 52 can be fitted with its own plug cap 66.

Referring now to Figures 10, 11 and 12, there are shown top views of the portion of storage base 28 including ejector pinion 34. These figures illustrate the dispensing sequence for containers 52. As in the preceding figures, the numbers shown in the centers of respective containers 52 indicate the dispensing sequence of containers 52. As shown in Figure 10, the first container is engaged in a concave portion of ejector pinion 34. This first container 52 is positioned along strip 50 in accordance with the details shown in Figure 3 with a spacing  $s$  between containers #1 and #2, the distance between concave portions of ejector pinion 34 also being equal to said length  $s$ . Ejector pinion 34 rotates in the direction shown by arrow 68. Figure 10 shows the

position of containers #1, #2 and #3 just before ejector pinion 34 is rotated its quarter turn to dispense container #1. In Figure 11, ejector pinion 34 has been rotated 1/8th turn from its starting position and container #2 is already 5 engaged in the next concave portion of ejector pinion 34. Figure 12 shows ejector pinion 34 rotated a full quarter turn from its position shown in Figure 10 and with container #1 dispensed through opening 56 of storage base 28. For the 10 sake of drawing convenience, in Figure 11, strip 50 is shown with some "slack" around Fig. 70 of ejector pinion 34. In reality, there would be little slack since the spacing S between containers is carefully selected so that there 15 will be no slack. As shown in Figures 10-12, ejector pinion 34 conforms to the space defined by outer wall 32 and inner partition 30 so that there is very little clearance between the tips 70 of ejector pinion 34 and the wall and partition 20 portions of storage base 28. This protects the containers from being tampered with or removed before ejector pinion 34 is unlocked for dispensing. After a container 52 is dispensed, as 25 shown in Figure 12, the container 52 may be removed from strip 50 and the protruding portion of the strip 50 can be torn off at the edge 33 of wall 32 and discarded.

The operation of field unit 24 is under 30 the control of a microprocessor. The microprocessor periodically unlocks a locking mechanism so that the user can manually dispense the next container in sequence. However, the operation is considerably more sophisticated than merely unlocking at predetermined intervals of

time. It can unlock based on a predetermined formula including predetermined intervals and also as a function of when actual dispensing has taken place. Therefore, it is important that the microprocessor know exactly when the user has dispensed a container.

5 Referring now to Figures 13-16, there are shown drawings of portions of the field unit 24 for annunciating that a dispensing operation has been completed and for preventing reverse rotation of ejector pinion 34.

10 Referring first to Figure 13, ejector pinion 34 is driven by a drive shaft 72 having cams 74 and 76 (Cam 74 is not fully visible in Figure 13). Drive shaft 72 is rigidly coupled to knob 36 which is rotated by the user to cause a dispensing operation. Cams 74 and 76 engage 15 spring loaded switch actuators 78 and 80 which in turn operate ejector switches 82 and 84. Cams 74 and 76 each include two cam portions spaced 180° apart around drive shaft 72. They are oriented around shaft 72 so that closest portions of cams 74 and 76 are spaced 90° from one another around periphery of drive shaft 72 so that they will cause a closure of switches 82 and 84 at 90° 20 intervals of the rotation of drive shaft 72. Figure 13 shows a position of drive shaft 72 whereat actuator 78 is engaged with cam 74 thereby turning switch 82 "on". As shown in Figure 13, at the time switch 82 is "on", actuator 80 is not 25 engaged with cam 76 because cam 76 is out of position of drive shaft 72 so that it cannot be engaged. Therefore, actuator 80 is not engaged 30 with cam 76 and switch 84 is therefore "off".

Figure 14 shows the same components as shown in Figure 13, but later in time, after drive shaft 72 has been rotated 90 degrees, so that cam 76 is engaged by actuator 80. As shown in Figure 14, when actuator 80 is engaged in cam 76, switch 84 turns "on". Cam 74 is then out of position so that actuator 78 cannot engage it. Therefore, switch 82 is "off".

Referring now to Figures 15 and 16, this process of signalling a complete dispensing 10 operation is further illustrated.

Referring now to Figure 15, actuator 78 is shown engaged with cam 74, thereby causing switch 82 to be "on". This corresponds to the position shown in Figure 13. At the same time, 15 actuator 80 is not engaged with cam 76 and therefore switch 84 is "off".

Figure 16 shows the same components as shown in Figure 15, but 1/4 rotation of drive shaft 72 later. Actuator 78 is not engaged with 20 cam 74, but actuator 80 is engaged with cam 76. Therefore, switch 82 is off and switch 84 is "on". The "on" and "off" status of ejector 25 switches 82 and 84 signal to the microprocessor when a dispensing operation is complete. This corresponds to completion of a 1/4 turn of drive shaft 72 rotation.

In addition, the shape of the cam depressions on drive shaft 72 are such that they prevent reverse shaft rotation when an actuator 78 or 80 is seated in its corresponding cam. The seating action is abrupt and concurrent only with a complete 90° drive shaft rotation to avoid ambiguous signalling. The microprocessor is programmed to electrically deactivate a switch 82

or 84 immediately after it has been mechanically activated. By using two switches that are alternately enabled and activated by a completed dispensing operation, erroneous multiple signals that could occur if only one switch were used are 5 avoided.

The unlocking mechanism will be discussed with reference to Figures 17, 18 and 19. Ejector pinion 34 interacts with a locking wheel 86 which controls a locking wheel switch 88 for signalling 15 the microprocessor as to the "locked" or "unlocked" status of field unit 24. As shown in Figure 17, locking wheel 86 includes a notched portion 90. The locking wheel 86 is positioned such that notched portion 90 can interact with 20 locking pins 58 of ejector 34. Viewed from above, the locking wheel 86 is above that portion of ejector 34 including tips 70, as shown in Figures 18 and 19. Locking wheel 86 is rotated by interaction with locking pins 58 between those 25 positions shown in figures 17 and 19. A rotary solenoid 212, not shown in this Figure, can reset the locking wheel 86 from its locked position in Figure 19 to its unlocked position in Figure 17.

As shown in Figure 18, a locking pin 58 30 of ejector pinion 34 engages notch 90 in locking wheel 86 and rotates the locking wheel 86 towards the "locked" position. Thus, rotating ejector pinion 34 during a dispensing operation, causes locking wheel 86 to change positions. Engagement 35 of the next locking pin 58 with locking wheel 86, as shown in Figure 19, prevents further ejector pinion rotation. This automatically locks the dispensing device upon completion of a dispensing operation. Thus, Figure 19 illustrates a "locked"

position, resulting from the counter-clockwise rotation of locking wheel 86 as a result of clockwise rotation of ejector pinion 34. When it is time to unlock the dispensing device, the microprocessor actuates the solenoid to rotate locking wheel 86 backwards, i.e., clockwise, into the unlocked position, shown in Figure 17, thereby allowing the user to carry out the next dispensing operation.

Referring now to Figure 20, there is shown a view of locking wheel 86 coupled so as to be operated by a solenoid 212. A pulse from the microprocessor to solenoid 212 causes locking wheel 86 to rotate from the position shown in Figure 19 to the position shown in Figure 17.

Referring now to Figures 21 and 22, the container stop operation will be explained. Container stop pin 92 is mounted in a bottom plate 94 of field unit 24. Ejector pinion 34 includes notches 96 for clearing the stop pin during ejector pinion 34 rotation. In effect, stop pin 92 prevents further ejector pinion 34 rotation until the dispensed container 52 (shown in Figure 21) is removed. Thus, pin 92 prevents inadvertent or intentional attempted insertion of containers back into the unit which could jam the dispensing mechanism.

Referring now to Figure 23, there is shown a cross sectional view of field unit 24 in an assembled condition showing both dispensing module portion 46 and storage base 28. Slotted extension 40 of partition 30 is engaged by a cam lock 96 for securing dispensing module 46 and storage base 28 in an assembled condition. The electronic subsystem including the microprocessor

is formed on a circuit board 98 within dispensing module portion 46. The electronic subsystem is powered by a battery 200. A second battery 202 provides power for operating the solenoid. 5 Circuit board 98 has mounted thereon a liquid crystal display 204 for displaying information to the user through a window 206 in the upper surface of dispenser module portion 46. Knob 36 for effecting a dispensing operation is shown in the upper right corner of this figure. Dispensing module portion 46 also includes a piezo electric alarm 208 for sounding an audible alarm through an opening 210 to alert the user that it is time to dispense a dose of medication.

Referring now to Figure 24, there is 15 shown a view looking up into the dispenser module portion 46 of field unit 24. Ejector pinion 34 is not shown in this figure. Three conductor connector 216 provides interconnection to interface unit 22. Push button switch 214 allows 20 the user to reset the microprocessor 100 to signal a base unit 20 request.

#### Field Unit 24 Electronic Subsystem

Referring now to FIGURES 25(A) and 25(B), there is shown a schematic diagram of the 25 electronic subsystem hardware of a field unit 24. The functions of electronic subsystem are as follows:

1. It provides RAM (random access memory) for approximately 131 bytes (or more) of information. Fifty of these bytes correspond to 50 alphanumeric characters that define dosing schedule and identifying data. The remaining 81 bytes

of memory are used to store one byte which holds the dosage taken count and 80 bytes that contain the date and time data when up to forty dosages have been taken. The size of the RAM required is a function of the number of dosages that can be delivered and the amount of identifying data desired.

5. 2. It provides information as to the real or related time of day and date. This information is made accessible to the microprocessor for the purposes of recording dosing times and for schedule checking.

10. 3. It provides signalling element(s) to indicate to the microprocessor when a dosage has been dispensed.

15. 4. A signalling element is provided to indicate that the ejector locking mechanism is in its locked position.

20. 5. A communications path is provided for sending data to and receiving data from interface unit 22 and base unit 20.

25. 6. A clock display with its associated driver circuitry is provided to display the next dosing time (including AM/PM and proper day indicators).

30. 7. An ejector unlock mechanism and associated driver circuitry is provided such that access to dosages is under field unit electronics control.

8. An audible alarm with its associated circuitry is provided such that the monitor user can be alerted to an impending dosing time.

9. Programmable logic and control circuitry are provided for integrating the above eight functions into an effective unit.

These functions are carried out by the electronic subsystem which is microprocessor-based and under 5 the control of software flow charted in FIGURE 26 and listed in Appendix I. The electronic subsystem features low power consumption such that it can operate from a single small battery for a period of time that will accommodate the longest 10 possible dosing schedule that could be programmed into the unit. Solenoid 212 is powered by a separate solenoid battery 202 so that voltage swings due to solenoid operation will not affect electronic subsystems. Battery operation affords 15 maximum portability and allows more convenient refrigeration, if required. The electronic subsystem has high noise immunity so that operation is not affected by spurious inputs, ambiguous data and address bus signal levels, or 20 supply voltage fluctuations.

The electronics subsystem provides the above-listed functions and features in the following manner.

The programmable logic and control 25 circuitry along with 112 bytes of RAM (random access memory) are provided by a Motorola MC146805E2 microprocessor unit 100, a NMC27C16 EPROM 102, a 74C00 address decode unit 104, and a 74HC373 Address Latch 106. The microcomputer 30 supports the minimum volume requirement by including on one chip 112 bytes of user RAM, timer circuitry, 16 input/output lines, and the means to simulate a UART (universal asynchronous receiver/transmitter) communications interface to

the interface/base units. Of the 112 bytes of user RAM available, one byte contains the dosage taken count, 80 bytes are used to store up to 40 sets of delivered dosage date and time data, and the remaining 31 bytes are used for intermediate 5 results and stack space. Up to 2048 bytes of program storage is provided by the UVEPROM (ultraviolet erased, electrically programmable, read-only memory). The 74C00 quad NAND gate decode unit and the 74HC373 latch allow the 10 microprocessor to properly access the EPROM.

The timekeeping function is provided by the Motorola MC146818 real time clock plus RAM 108 and a 32.768 kHz crystal oscillator circuit 110. The real time clock retransmits the 32.768 kHz 15 signal it receives from the crystal oscillator to supply the clock input the microcomputer requires. Crystal oscillator accuracy is approximately  $\pm .005\%$  which amounts to an error of about 3 minutes in forty days, the maximum usage period as 20 presently designed. Although the real time clock resolves time to the second, our present system only uses one minute resolution as this is more than sufficient precision for the immediate application. Another function of the real time 25 clock is to, by means of its programmable alarm circuitry, supply a once-per-minute interrupt signal to the microcomputer's timer input where a once-per-minute timer interrupt is generated. System integration is supported by the 50 bytes of 30 user RAM included in the real time clock. These 50 bytes of memory are used to store the identifying and dosing schedule data sent to the field unit during the monitor loading operation.

Microswitches 82, 84, operated by activators 78 and 80, respectively, riding on ejector drive shaft cams 74 and 76, provide the signalling means to indicate the delivery of the next dosage. The ejector drive shaft cams 74 and 5 76 and the microswitches' 82 and 84 orientation are such that the microswitches are alternately operated as dosages are sequentially delivered. By alternatively enabling the two microswitches 82, 84 electrically by means of output lines PA7 10 and PA6, a reliable indication of dosage delivery without danger of spurious, multiple signals is accomplished.

A locked ejector condition is signalled to the microcomputer by means of microswitch 88 15 activated by the ejector locking wheel and connected to input line, PA1.

Communications to the field unit are brought in on input line PA0, and data leaves the microcomputer through output line PA5 on its way 20 to the interface and base units. Communication protocols are provided by UART programs in the EPROM. Baud rate generation is derived from the microcomputer clock frequency. Serial, rather than parallel, formats are used to simplify the 25 communications interface and to permit the widest possible application to a variety of possible base units. The data format presently preferred is 110 baud rate, 8 bit word length, no parity bit, 1 stop bit, and XON/XOFF status disabled.

30 Liquid crystal display 204 with an ICM7211AM display driver 114 is used to provide next dosing time information to the user. Six output lines, PB0-PB5, are used to update the

driver and display after a dosage has been delivered.

Rotary solenoid 212 is used to release (unlock) the ejector locking mechanism under microcomputer control. A separate 4.2 volt 5 battery 202 is used to energize the solenoid circuit since the large current draw causes voltage spikes that would interfere with proper microcomputer operation if a common battery were used. ULN2069 quad Darlington switches 112 10 provide a high current buffer for the microprocessor control line PB6.

The audible alarm function comprises a piezoelectric element 208 and driver circuitry 116. The driver circuit 116, including a 15 transistor 118 and three resistors, serves to drive the piezoelectric element into oscillation, thereby producing an alarm.

Low power consumption is attained by using 20 1. All CMOS (complementary metal oxide silicon) circuitry. 2. A relatively slow clock rate (32.768 kHz). 3. Liquid crystal type clock display. 25 4. Piezoelectric type alarm element.

Consequently, a TR133 4.2 volt mercury battery 200 can power the entire circuit, exclusive of the solenoid, under worst case conditions, and for the maximum period of forty days and still retain a 30 large reserve charge.

High noise immunity is attained by using:

1. All CMOS circuitry with its wide noise margins and wide supply voltage limits.

2. Use of a separate battery for solenoid power.
3. Serial communications with error checking routines.

Minimum volume is attained by using:

- 5 1. Microcomputer on a chip. The MC146805E2 contains a microprocessor, 112 bytes of user RAM, timer, and 16 I/O lines, and can be programmed to perform the functions of an UART.
- 10 2. Multifunction real time clock. The MC146818 includes 50 bytes of RAM and an alarm interrupt.

Further integration and volume reduction is certainly possible through presently, or soon to be, available VLSI (very large scale integration) components that combine the microcomputer and real time clock functions, or the microcomputer and ROM functions, or even the microcomputer, ROM, and display driver functions. The ultimate in integration is also possible by means of customized CMOS gate arrays that could conceivably contain all the integrated circuit packages presently shown in our present design.

#### Field Unit Software

25 Referring now to FIGURE 26 there is shown a flowchart of the software associated with the FIGURE 25 hardware. A detailed program listing is set forth in Appendix I.

30 Program execution begins either after a power on reset (Step 300) (i.e. installation of a battery) or upon a hardware reset (Step 304) (i.e. pushing a reset switch 214) (see Figure 25A) A power on reset is not meaningful except that it

insures an orderly configuration of the microprocessor inputs and outputs immediately without the need of further operator action. After a power on reset, the program halts at a safe point (no outputs activated) and waits for 5 the proper beginning of operation.

Normal program execution begins when the reset switch is pushed by the operator to signify a base unit request (see Step 304). This request may be either to load the field unit with data 10 prior to use by the patient or it may be to have the field unit unload the data collected during the term of the patient's use of the Monitor. In either case the first action taken is to configure the microprocessor's input and output ports for 15 proper operation. This routine is named "Reset" (Step 302).

Next, in the "Recogn" (recognition) routine (Step 306), the field unit first sends an ASCII "R" ("ready") to the base unit to indicate 20 that communications may start and then waits to receive an ASCII character from the base unit in order to identify what function is being requested. If the received character is a "L", then the program jumps to the "Load" routine (Step 25 308). If the character is an "U", then the program jumps to the "Unload" routine (Step 310). If the character received is neither a "L" nor an "U", then a problem has occurred during communications and the program goes to the 30 "Badcom" ("bad communication") section (Step 312).

The "Badcom" routine sends a "?" to the base unit to alert it to the communications problem and then the program jumps to "Wait" (Step

314) where it waits for another push of the reset button to restart the program.

When the field unit recognizes a base unit request to "Load", it proceeds to receive, echo, and store 50 bytes (characters and numbers) of data sent by the base unit. This data includes patient and study identifying information and the dosing parameters data. The information is received as ASCII coded characters that are echoed to the base unit to insure accurate data transfer and then stored in the real time clock user RAM area for later use. The "Load" routine also allows the operator to verify the proper operation of the field unit's alarm and unlock functions before placing the unit into service.

After loading is complete the program enters the "Start" routine (Step 316). Here the real time clock is set to the actual time and is configured to provide a once-a-minute timer interrupt to the microprocessor. Registers in the microprocessor are initialized, the liquid crystal clock display 204 is set to show the first scheduled dosing time and finally, the real time clock is started running. The program then goes to the "Minute" section (Step 318) where the field unit begins user related operations.

In the "Minute" routine, which is reached once per minute via a timer interrupt, the microprocessor first reads the real time clock and stores the present hours and minutes to compare against the events schedule. The following checks are made and appropriate action taken:

1. Is it midnight? If so, increment day counter.

2. Should the piezoalarm be activated? If so, sound alarm 4 times.
3. If the ejector should be unlocked and is not, a pulse is sent to the solenoid to reset the locking wheel.

5 After completing these tests, the program exists to the "Wait" routine.

For all but a few seconds each minute the program is idling in the "Wait" routine. While in this routine, the microprocessor is in its "Wait" operating mode which disables all functions except the ability to respond to interrupts and resets. This results in very low power consumption which allows the field unit to operate on a small battery for a period of at least 40 days. While 15 in this state, the microprocessor performs no task and simply waits for one of three events to occur.

Once every minute the real time clock will initiate a microprocessor timer interrupt (Step 320) that causes the program to exit "Wait" 20 and go to "Minute" where the alarm and unlock checks will be made as described above. Upon completion of the "Minute" functions, the program returns to "Wait" and awaits the next interrupt.

The delivery of a dosage and the 25 accompanying activation of an ejector switch 82 or 84 (Step 322) will also cause the program to exit "Wait" by means of activating the microcomputer's external interrupt line. In this case the program jumps to "Dosage" (Step 316) where:

- 30 1. The dosage counter is incremented.
2. Date and time of dosage delivery data is stored in the microprocessor's user RAM.
3. The program jumps to "Minute" where the events schedule is checked.

After these tasks are completed the program once again returns to "Wait" to await the next interrupt or reset.

5 The third method of exiting "Wait" is the activation of the reset switch, signalling a base unit request. The servicing of a "Load" request was described above. An "Unload" request is now described.

At the end of the dosing period the field unit is returned to the doctor by the patient.

10 The base unit program for field unit interrogation will request the operator to push the reset switch. The field unit program exits the "Wait" routine, passes through "Reset" to the "Recogn" section where the unload request is recognized,

15 and then jumps to the "Unload" routine. This part of the program sends the original 50 bytes of identifying and dosing schedule data stored in the real time clock RAM back to the Base Unit. The 81 bytes of dosing data stored in the microprocessor's RAM are then sent to the base unit. The field unit checks for an accurate echo from the base unit after each data byte is sent. After data transmission is complete the field unit program goes back to "Wait". If any echo shows

20 that a data transfer error has occurred, the "Unload" program is aborted and a jump is made to "Badcom" where an error flag is transmitted as described earlier.

#### Interface Unit

30 Referring now to FIGURE 27 there is shown a schematic diagram of interface unit 22 and the communication lines of base unit 20.

The purpose of the interface unit 22 is to provide signal level shifting such that the field unit can send and receive serial communications to and from any base unit 20 having an RS-232-C standard serial communications port. By 5 means of this interface unit 22 the compliance monitor system then has the flexibility of using almost any computer with the proper software for its base unit 20 since the use of RS-232-C serial ports is so prevalent.

10 Under the EIA (Electronics Industries Association) RS-232-C standard, binary state 1 (one) signals are transmitted as a voltage between -5 and -15 volts. Binary state 0 (zero) signals are transmitted as a voltage between +5 and +15 15 volts. In the field unit the binary state 1 is at +4.2 volts and the binary state zero is at 0 volts ("ground"). Thus, the interface unit must be capable of converting the field unit's +4.2 volt transmissions into -5 to -15 volt signals, and 20 must convert 0 volt levels into +5 to +15 volt signals for proper reception by the base unit RS-232-C port. Conversely, the -5 to -15 volt signals from the base unit port must be changed to approximately +4.2 volts, and +5 to +15 volt 25 signals must be changed to 0 volts (ground) for use by the field unit. The base unit presently preferred (Radio Shack Model 100) outputs +/-5 volts on its RS-232-C transmission lines.

Interface unit 22 includes the following 30 primary elements to provide the functions described above: a multi-voltage power supply including a power supply element 400, preferably a CALEX 22-120, a regulator 402, preferably a 7805, a RS-232-C line receiver 410, a RS-232-C line

driver 420, and connectors and cables to interconnect the base 20, interface 22, and field units 24. The power supply converts 120 volts AC input power into +12, -12, and +4.3 volts DC outputs for use by the line driver and receiver

5 circuits. One fourth of a MC1488 Quad Line Driver takes 0 and +4.2 volts DC signals from the field unit's transmitting port (MC146805E2, pin 9, PA5) and converts them to +12 and -12 volts DC signals, respectively, for transmission to the base unit's

10 receiving line (RXR, pin 3). One fourth of a MC1489 quad line receiver takes +5 and -5 volts DC signals from the base unit's transmitting line (TXR, pin 2), and converts them to 0 and +4.3 volts DC signals, respectively, for transmission

15 to the field unit's receiving port (MC146805E2, pin 14, PA0).

The RS-232-C interface standard provides for up to 25 lines for control and data, but this system only requires use of three: line 2, TXR;

20 line 3, RXR; and line 7, GND. Similarly, only three lines are needed between the interface unit and field unit.

The interface unit 22 circuitry does not necessarily need to be housed in a separate cabinet. These electronics could be contained in the field unit except for the disadvantages associated with the increased volume required for the electronics and the additional batteries needed to meet RS-232-C line voltage

25 requirements. The interface electronics could also be contained in the base unit housing, especially since the required voltages are often already available. However, we presently separately house the interface electronics so that

other base units may be used without hardware modifications.

#### Base Unit Hardware

Referring now to FIGURE 28 there is shown a block diagram of base unit 20.

5       Base unit 20 provides the compliance monitor system user with a means of programming field units with the instructions necessary to control drug delivery and a means by which to retrieve data stored in the field unit at the end  
10      of the dosing program. Base unit 20 further provides a means for processing the recovered data and generating analytical reports detailing all system operations.

15      Base unit 20 is a computer system advantageously combining the following attributes:

- 20      1. ROM/RAM memory size sufficient to contain the LOAD-M and READ-M programs with their associated workspaces (approximately 12,500 bytes when written in BASIC) plus its own operating systems.
- 25      2. RS-232-C Serial communications interface -- for loading data to and unloading data from the interface/ field units.
- 30      3. Interface to a hard copy device -- usually a parallel printer port.
- 35      4. Display -- internal or external; CRT, LCD, etc. -- for prompting user.
- 40      5. Keyboard or other data entry device.
- 45      6. Hard copy unit -- usually a dot matrix printer capable of printing both text and graphics.

Other features of the base unit include:

1. A high level programming language (BASIC, FORTRAN, etc.) interpreter for ease of software development and revision.
- 5 2. BASIC interpreter in ROM -- eliminates the need for loading the system from, disk or tape before each operating session.
- 10 3. Sockets for application program ROMs -- eliminates the need for loading the application programs from disk or tape before each operating session; ROM does not require continuous battery backup; software is better protected from pirating.
- 15 4. Additional ROM/RAM memory space beyond the minimal requirement such that application programs for statistical analyses, protocol screening, etc. can reside in, and be run from, this one computer.
- 20 5. An on-board real time clock so that the operator need not repeatedly enter time and date information during field unit load and read operations.
- 25 6. A high level of system component integration -- for minimum space requirement, portability, battery operation, and lower cost.

The preferred embodiment uses a Radio Shack Model 100 portable computer 500 and an Epson RX-80 dot matrix graphics printer 510 to meet the above requirements. The Model 100 integrates all of the required functions, except that of the printer, plus several others into one very compact

and inexpensive unit. It contains 32K bytes of ROM where the BASIC interpreter resides. 32K bytes of RAM are available, part of which may hold the LOAD-M and READ-M application programs. This RAM is backed-up by a NICAD battery which retains 5 the programs in memory indefinitely when the AC adapter is used or for several days when the unit is operated from batteries. Future versions of the base unit will have the application programs stored in a second 32K byte ROM for which there is 10 a socket in the bottom of the computer. The programs could then never be lost due to loss of battery charge. Further, when programs are in ROM, they are stored in machine language or tokenized BASIC, thus affording better software 15 security.

The Model 100's input/output ports include a parallel printer port for sending output to the dot matrix printer and a RS-232-C serial communications port for communicating with the 20 interface/field units and, perhaps, with other computers. The serial port operates at several user-selectable baud rates including the relatively slow 110 baud rate. This rate is still fast enough to provide a convenient data transfer 25 rate while slow enough to allow the use of a battery conserving, slower clock frequency in the field unit.

Other I/O ports available, but not presently used, are a bar code wand input, a 30 cassette recorder interface, and a telephone modem. A bar code wand could be used with future models to take inventories required for drug control. The cassette recorder port provides a means for reloading the application programs into

memory if memory backup power is ever lost. The modem might be used to allow future field and base units to communicate remotely over phone lines.

The Model 100 has an on-board real time clock so that time and date information need be inputted or updated only infrequently.

The display function is provided by an internal 40 character by 8 line liquid crystal dot graphics display. Prompts and data may be presented in any combination of text and graphics.

The typewriter style keyboard includes cursor control and function keys for easy data entry and program selection.

The Epson RX-80 dot matrix graphics printer has both text and graphics print modes and uses 8½ x 11" continuous forms. Data and instructions from the Model 100 are handled by a standard Centronics compatible, 8-bit parallel interface.

Of course, many other computer and peripheral combinations could provide the required base unit functions. The Model 100 and RX-80 units were chosen because they offered the best combination of features and low cost then available. Another method of reducing system cost would be to provide software packages for several common computer systems that meet base unit requirements. The customer then would be able to make use of already existing computer hardware.

#### Base Unit Load Software

Referring now to FIGURE 29 there is shown a flowchart of the base unit "LOAD-M" software for storing a medication schedule into a field unit

24. A detailed program listing is set forth in Appendix II.

The LOAD-M program is selected by moving the main menu cursor over LOAD-M and pressing the "Enter" key. The program starts automatically and 5 prompts the user through all loading operations. Even the most inexperienced operator should be capable of reliable data entry after only minimal training. Proper format checks and escape sequences prevent and correct most erroneous 10 inputs.

LOAD-M is selected after field unit 24 has been loaded with dosages and before being given to the patient. The program collects the 15 study and patient identifying data and the dosage schedule and control data through keyboard responses to instructions prompted on the liquid crystal display. This data is loaded into the field unit by way of the interface unit. Finally, a hard copy report of the loaded data is printed.

20 More specifically, operation is as follows:

1. MMS Logo, Copyright Notice, and "Monitor Loading Routine" Displayed.
2. Data Entry - Identifying and schedule 25 data are entered.
  - a. Study ID# - 1 to 6 alphanumeric characters. If more than six characters are entered, only the first six are used. Other formats could be used.
  - b. Patient ID# - 1 to 6 alphanumeric characters. If more than six characters are entered, only the first six are used. Other formats could be used.

- c. Daily dosing schedule - 1 to 4 "on the hour" dosing times. Each selected time must be no earlier than the previous dosing time. Selection is made by moving the cursor over the desired hour and pressing "Enter". Once four times are entered, the program automatically jumps to the next operation. An "entry complete" input is required when less than 4 dosing times are entered.
- 5
- d. First Dosage Time - The selected dosage schedule is displayed on the LCD screen and the starting dosage is chosen by moving the cursor over the desired time and pressing "Enter".
- 10
- e. Starting Day Offset - If dosage taking is not to begin before the end of the current day, the number of days before dosages are to be taken should be entered. This feature allows the monitor system operator to load field units in advance, whenever convenient.
- 15
- f. Number of Doses Loaded - Knowing the number of doses loaded allows field unit 24 to stop alarm and display functions after the last dose is delivered.
- 20
- g. Monitor Serial # - 1 to 6 alphanumeric characters. If more than six characters are entered, only the first six are used. An "L" in the first position indicates that the field unit being loaded has the computer controlled unlock feature and that the unlock period must be inputted. Other formats could be used.
- 25
- 30



interpret a different set of schedule parameters.

3. Field Unit Loading/Testing - Entered data is moved into field unit.

- 5 a. First, LOAD-M disassembles and converts the entered string values into 50 bytes of data suitable for transmission to and use by the field unit.
- 10 b. The operator is then prompted to connect the interface unit (which is connected to the base unit at the RS-232-C port) to the field unit. When the field unit's reset switch is pushed the base unit and field unit begin
- 15 c. communications. The entire loading operation is automatic and needs no operator intervention. The LOAD-M program signals to the field unit that a load operation is beginning, waits for a "Ready" reply, and then sends the 50 bytes of data in a sequence expected by the field unit. After each byte is sent, the base unit checks that the field unit has echoed the proper data indicating good data transmission. If a bad echo is received, the data transfer is aborted and restarted.
- 20 d. After loading is complete, the operator is prompted to check alarm and unlock features of the field unit if so desired. By pressing "B" the alarm should sound. By pressing "U" the unlock solenoid should activate.
- 25
- 30

d. When loading and testing are complete, LOAD-M prompts the operator to turn off and disconnect the interface unit, and ready the printer.

5 4. Print Permanent Record of the Loading Operation.

10 a. The program proceeds to automatically print a one page record of the loading operation (see sample in Appendix II). All inputted data is repeated and the time and date of loading is recorded. This record then serves to document the loading phase of the monitoring program for use in the patient's, program, and physician's files.

15

20 5. Program Exit.

a. The operator is asked whether there is another field unit to be loaded. If so, the program jumps to the beginning (just after the logo and copyright notice) to restart. If there are no more field units to load, LOAD-M is exited and program control returns to the Model 100 main menu where another program may be selected if desired.

25

Note: The LOAD-M operations require only approximately two minutes to complete (per field unit).

Base Unit Read Software

30 Referring now to FIGURE 30 there is shown a flowchart of the base unit "READ-M" software for

debriefing a field unit 24 and preparing a compliance report. A detailed program listing and a sample compliance report are set forth in Appendix III.

5 The READ-M program is selected by moving the main menu cursor over READ-M and pressing the "Enter" key. The program starts automatically and prompts the user through all unloading operations. Even the most inexperienced operator should be  
10 capable of debriefing field units after only minimal training.

15 READ-M is selected after the patient returns the field unit at the end of the dosing program. The program unloads from the field unit, by way of the interface unit, the dosage delivery data as well as the previously loaded identification and schedule control data. The data is analyzed, presented on the LCD, and printed on a one or two page report. The format of the LCD and  
20 hard copy reports is such that the level of compliance is evident at a glance.

More specifically, operation is as follows:

1. MMS Logo, Copyright Notice, and  
25 "Monitor Debriefing Routine" are displayed.
2. Unload Field Unit - Stored data is moved into base unit.
  - a. Operator is prompted to connect the interface unit (which is connected to the base unit at the RS-232-C port) to the field unit, turn on the interface unit, and press the field unit's reset switch.
  - b. After the reset switch is pressed, the  
35 base unit and field unit begin

communications through the interface unit. The entire unloading operation is automatic and needs no operator intervention. The READ-M program awaits a "Ready" signal from the field unit, then signals that an unload operation is beginning. Having established communications, the field unit sends 131 bytes of data to the base unit. The 5

10 first 50 bytes are the same data originally stored during the load operation. The 51st byte sent contains the count of dosages taken. The final 80 bytes, arranged as 40 pairs, are 15 compressed representations of the dosage delivery time and date data. If all 40 dosages were not taken, data pairs beyond the dosages taken point contain meaningless data. After each data byte 20 is received by the base unit, it is echoed to the field unit to verify proper data transfer. If the field unit receives a bad echo, it sends an ASCII 25 '?' to the base unit which causes the READ-M program to restart the unload operation.

### 3. Assemble Identifying and Schedule

#### Data.

30 a. The first 50 bytes received are assembled into the proper string and numeric variables that represent the schedule and identifying data originally loaded into the field unit by the LOAD-M program.

## 4. Display Compliance Report.

5 a. The READ-M program next unpacks the dosage delivery data and presents an analysis of the compliance levels along with the identifying and schedule data on the liquid crystal display.

10 Compliance is shown by plotting the dosage number against the actual dosing time error. The five error levels used are:

15 - More than 2 hours early  
- Less than 2 hours early  
- Within plus or minus one hour  
- Less than 2 hours late  
- More than 2 hours late

15 An asterisk is plotted at the appropriate error level for each of the dosages taken.

## 5. Print Hard Copy of the Compliance

## 20 Report.

25 a. The compliance report described in 4 is output to the printer. However, instead of plotting an asterisk, the actual dosing time in hours and minutes is plotted at the appropriate error level for each of the dosages taken.

30 Additionally, if the actual dosing time is not on the proper day, the number of days early or late is printed after the dosing time. The hard copy report will require one or two pages depending upon the number of dosages taken. This record then serves to document the

debriefing phase of the monitoring program for use in the patient's, program, and physician's files.

5 Note: Other methods of presenting the compliance analysis (e.g. using four hour error bands, statistical analyses, etc.) are equally valid. The READ-M program quickly shows compliance levels "at-a-glance" and assumes that more detailed analyses can be made in other programs.

10

15 6. Program Exit.

a. The operator is asked whether there is another field unit to be unloaded. If so, the program jumps to the beginning (just after the logo and copyright notice) to restart. If there are no other field units to unload, READ-M is exited and program control returns to

20 the Model 100 main menu where another program may be selected if desired.

Note: The READ-M operations require only approximately two minutes to complete (per field unit).

25 Further Enhancements

- Additional base unit software can be provided for patient screening per the drug therapy protocol during the loading operation in medication efficacy studies.

- Additional base unit software can be provided to do statistical analyses of the compliance data for one or more patients.

5 - By means of a keyboard or card reader one field unit could keep track of dosage delivery to several patients by requiring the entry of access and identifying codes.

10 - A modem contained within, or attached to, the field unit would allow remote uploading of data to the base unit from the field unit and downloading of new instructions to the field unit from the base unit.

15 While the invention has been described in connection with what is presently considered to be the most practical and preferred embodiments, it is to be understood that the invention is not to be limited to the disclosed embodiments but on the contrary, is intended to cover various modifications and equivalent arrangements included within 20 the spirit and scope of the appended claims which scope is to be accorded the broadest interpretation so as to encompass all such modifications and equivalent structures.

CONTROLLED DISPENSING DEVICE  
FIELD UNIT PROGRAM LISTING

APPENDIX I

MONITOR5.TXT

5 REV. 07  
08.22.84.LEP

CLOCKS: 32.768 kHz (F1) INTO 146818 FROM CRYSTAL OSCILLATOR  
32.768 kHz (F2) (F1/1) INTO 146805E2 FROM 146818  
6553.6 Hz (F3) (F2/5) BUS FREQUENCY

10 BUS CYCLE PERIOD = .000152588 SEC. (1/F3)

FOR 110 BAUD:

# TOTAL CYCLES / BIT PERIOD = 60 = 59.57818 = 6553.6/110  
(.7% ERROR)

PORT ASSIGNMENTS: PORT A: 0000

15 DDRA : 0004 00 UPON RESET

FC UPON INITIALIZATION

BIT 0 = IN(0) = RS-232C INTO MONITOR (FROM LINE 2, TXR)  
MARK(-12v)=1(+4.3v) SPACE(+12v)=0(GND)  
SET MODEL 100 FOR 28N1D

20 1 = IN(0) = SPROCKET LOCK STATUS SWITCH

HIGH = LOCKED LOW = UNLOCKED

2 = OUT(1) = DEBUG USE ONLY (GREEN LED - 'MINUTE')

3 = OUT(1) = DEBUG USE ONLY (RED LED-'WAIT' & 'DOSAGE')

4 = OUT(1) = SOLENOID - UNLOCK

25 5 = OUT(1) = RS-232C OUT OF MONITOR (TO LINE 3, RXR)

1(+4.3v)=MARK(-12v) 0(GND)=SPACE(+12v)

SET MODEL 100 FOR 28N1D

6 = OUT(1) = MICROSWITCH #2 - DRUG DELIVERED

7 = OUT(1) = MICROSWITCH #1 - DRUG DELIVERED

PORT B: 0001  
DDRB : 0005 00 UPON RESET  
FF UPON INITIALIZATION

BIT 0 = OUT(1) = LCD DATA, B0  
 1 = OUT(1) = LCD DATA, B1  
 2 = OUT(1) = LCD DATA, B2  
 3 = OUT(1) = LCD DATA, B3  
 4 = OUT(1) = LCD DIGIT SELECT, DS1  
 5 = OUT(1) = LCD DIGIT SELECT, DS2  
 6 = OUT(1) = LCD CHIP SELECTS  
 7 = OUT(1) = PIEZO ALARM

146818 REGISTERS:

REGISTER A(\$010A) - 00101010 = 2A = 32.768 kHz CRYSTAL

15.625 msec PI

15 64 Hz SOW (NOT USED)

BIT 0 - 3 RATE SELECT (0000 = 15.625 mSec PI,  
64 Hz SQW)

4 - 6 DIVIDER BITS (010 = 32.768 kHz CRYSTAL)

7 UPDATE IN PROGRESS FLAG (READ ONLY)

RECEIVER 3(4105) 00100110 20 ASN, FILE DISABLED,  
AIE ENABLED, UIE DISABLED,  
SQWE DISABLED, BINARY,24,  
NO DSE  
SET BIT 7(HOLD)(\$A6) DURING TIME INITIALIZE

BIT 0 - DAYLIGHT SAVINGS ENABLE (0=DISABLE)  
1 - 24/12 HOUR FORMAT (1=24)  
2 - DATA MODE (1=BINARY)  
3 - SQW ENABLE (0=DISABLE)  
5  
4 - UPDATE ENDED INTERRUPT ENABLE (0=DISABLE)  
5 - ALARM INTERRUPT ENABLE (1=ENABLE)  
6 - PERIODIC INTERRUPT ENABLE (0=DISABLE)  
7 - SET (1=HOLD 0=RUN)

REGISTER C(010C) - READ ONLY (CLEARED BY A READ)  
10  
BIT 6 - PERIODIC INTERRUPT FLAG  
5 - ALARM INTERRUPT FLAG

0  
REGISTER D(010D) - READ ONLY (NOT USED)

146818 RAM: 0100 SECONDS  
15  
0101 SECONDS ALARM  
0102 MINUTES  
0103 MINUTES ALARM  
0104 HOURS  
0105 HOURS ALARM  
20  
0106 DAY OF WEEK  
0107 DATE OF MONTH  
0108 MONTH  
0109 YEAR  
010A REGISTER A  
010B REGISTER B  
010C REGISTER C  
010D REGISTER D

---

(USER RAM) (ALL DATA IS ASCII)

(NUMERIC VALUES ARE REPRESENTED BY ASCII EQUIVALENT)

010E D\$(0) SI\$ LEFT ]  
010F D\$(1) SI\$ ]  
5 0110 D\$(2) SI\$ ]  
0111 D\$(3) SI\$ } STUDY ID#  
0112 D\$(4) SI\$ ]  
0113 D\$(5) SI\$ RIGHT]  
0114 D\$(6) PI\$ LEFT ]  
10 0115 D\$(7) PI\$ ]  
0116 D\$(8) PI\$ ]  
0117 D\$(9) PI\$ } PATIENT ID#  
0118 D\$(10) PI\$ ]  
0119 D\$(11) PI\$ RIGHT]  
15 011A D\$(12) SN, # OF DOSAGES/DAY, 1-4  
011B D\$(13) SC(0) SCHEDULED DOSING HOUR (TARGET HOUR) (0-23)  
011C D\$(14) SC(1)  
011D D\$(15) SC(2)  
011E D\$(16) SC(3)  
20 011F D\$(17) D1, FIRST DOSAGE POINTER, 0-3  
0120 D\$(18) SN\$ LEFT ]  
0121 D\$(19) SN\$ ]  
0122 D\$(20) SN\$ ]  
0123 D\$(21) SN\$ } MONITOR SERIAL#  
25 0124 D\$(22) SN\$ ]  
0125 D\$(23) SN\$ RIGHT]  
0126 D\$(24) UP, UNLOCK PERIOD (58,30,01, OR 61)  
0127 D\$(25) AP, ALARM PERIOD (58,45,30, OR 61)  
0128 D\$(26) DA\$ LEFT ]  
30 0129 D\$(27) DA\$ ]

012A D\$(28) DA\$ ]  
012B D\$(29) DA\$ ]  
012C D\$(30) DA\$ } LOADING DATE  
012D D\$(31) DA\$ ]  
5 012E D\$(32) DA\$ ]  
012F D\$(33) DA\$ RIGHT]  
0130 D\$(34) TM\$ LEFT ]  
0131 D\$(35) TM\$ ]  
0132 D\$(36) TM\$ ]  
10 0133 D\$(37) TM\$ ]  
0134 D\$(38) TM\$ } LOADING TIME  
0135 D\$(39) TM\$ ]  
0136 D\$(40) TM\$ ]  
0137 D\$(41) TM\$ RIGHT]  
15 0138 D\$(42) STARTING MINUTES (26 GOES TO 27 IN LOAD-M)  
0139 D\$(43) STARTING HOURS  
013A D\$(44) SD, STARTING DAY OFFSET  
013B D\$(45) TD, TOTAL # OF DOSAGES, 1 - 40 (26-27 IN LOAD-M)  
013C D\$(46) 0 (NOT USED)  
20 013D D\$(47) 0 (NOT USED)  
013E D\$(48) 0 (NOT USED)  
013F D\$(49) 0 (NOT USED)

## 146805 RAM MAP:

	0000	PORT A PORT A DATA REGISTER
	0001	PORT B PORT B DATA REGISTER
	0002	EXTERNAL MEMORY SPACE
5	0003	EXTERNAL MEMORY SPACE
	0004	DDRA PORT A DATA DIRECTION REGISTER
	0005	DDRB PORT B DATA DIRECTION REGISTER
	0006	EXTERNAL MEMORY SPACE
	0007	EXTERNAL MEMORY SPACE
10	0008	TIDATA TIMER DATA REGISTER
	0009	TCR TIMER CONTROL REGISTER
		TCR7 - INTERRUPT REQUEST (CLEARED BY RESET)
		TCR6 - INTERRUPT MASK (1=MASKED)
		TCR5 - EXTERNAL CLOCK SOURCE (1=EXTERNAL)
15		TCR4 - EXTERNAL TIMER PIN ENABLED (1=ENABLE)
		TCR3 - PRESCALER RESET TO 0 WITH A 1
		TCR2 - TCR0 - DIVIDE BY FACTOR (000= /1)

---

0010 ATEMP TEMPORARY STORAGE OF A  
TEMP. STORAGE OF DAY OF WEEK DATA  
FROM RTC READ

5 0011 CHAR CHARACTER BYTE FOR SEND C  
RECEIVED CHARACTER ASSEMBLY BYTE IN REC C  
@HOUR2 - 1

0012 COUNT BIT COUNTER FOR SEND C & REC C

0013 XTEMP TEMPORARY STORAGE OF X

0014 @HOUR TARGET HOUR (0-23)

10 0015 NEXTHR NEXT HOUR POINTER, 0-3

0016 DAYCNT ACTUAL DAY COUNTER (# RTC DAY OF WEEK CHANGES)

0017 @DAY TARGET DAY COUNTER (# OF NEXTHR WRAP-AROUNDS)

0018 HOURS ACTUAL HOURS DATA REGISTER - FROM RTC READ

0019 MINUTS ACTUAL MINUTES DATA REGISTER - FROM RTC READ

15 001A DAYWEK DAY OF WEEK REFERENCE

001B @HOUR2 UPCOMING TARGET HOUR

001C DOSTKN D\$(50), # OF DOSES DELIVERED

001D-006D D\$(51)-D\$(131), TIME AND DAY STORAGE  
(80 BYTES)

20 006E-007F STACK (17 BYTES)

## 146805 ROM MAP:

## MAIN ROUTINES:

1800 RESET UPON MONITOR RESET BY PUSHBUTTON SWITCH  
OR POWER UP

5 1820 RECOGN 'READY', LOAD OR UNLOAD, 'ERROR'

1840 LOAD READS DATA FROM BASE UNIT INTO MONITOR

18A0 START INITIALIZES AND STARTS RTC

1900 UNLOAD SENDS DATA FROM MONITOR TO BASE UNIT

1A00 WAIT POWER DOWN & WAIT FOR INTERRUPT OR RESET

10 1B00 MINUTE TIMER (RTC ALARM) INTERRUPT SERVICE  
ROUTINE (1/MIN)

1D00 DOSAGE EXTERNAL INTERRUPT (DOSAGE DELIVERED)  
ROUTINE

## SUBROUTINES:

1E00 SEND C SERIAL OUTPUT TO INTERFACE UNIT

CHARACTER MUST BE IN REG A BEFORE  
ENTERING ROUTINE

5

REG A IS ALTERED

CHARACTER IS IN 0010 ('ATEMP') AT END

110 BAUD, START, 8 DATA, NO PARITY, 1 STOP  
SET MODEL 100 FOR 28N1D

1E30 DELAY 30 CYCLE DELAY FOR SERIAL COMMUNICATIONS

10

ROUTINES

CALLED BY 'SEND C' AND 'REC C'

X IS ALTERED IF 'DELAY' NOT USED IN REC C  
OR SEND C

1E40 REC C SERIAL INPUT FROM INTERFACE UNIT

15

RECEIVED CHARACTER GOES INTO REG A

REG A IS ALTERED

110 BAUD, START, 8 DATA, NO PARITY, 1 STOP  
SET MODEL 100 FOR 28N1D

1E80 BADCOM BAD COMMUNICATION - SENDS '?' AND WAITS

20

1E90 UNLOCK UNLOCK SOLENOID ON FOR 50 mSec (IF LOCKED)

1EA2 BELL PIEZO ALARM ON FOR 100 mSec/ OFF FOR 500 mSec

1EC0 ADVTGT TARGET REGISTERS & LCD UPDATE TO NEXT  
DOSING HOUR

## SUBROUTINES (continued):

1F20 LCDOUT LOAD A DISPLAY DIGIT

1F30 RTCRED READ RTC HOURS, MINUTES, &amp; DAY OF WEEK

1F50 PACK PACK/STORE HR, MIN & RAM DAY DATA INTO 2 BYTES  
5 OF 146805 USER RAM

1F80 DASH PUT DASH IN HOUR DISPLAY

## INTERRUPT VECTORS:

	1FF6-1FF7	TIMER INTERRUPT FROM WAIT	- 1B00 ('MINUTE')
	1FF8-1FF9	TIMER INTERRUPT	- 1B00 ('MINUTE')
10	1FFA-1FFB	EXTERNAL INTERRUPT	- 1D00 ('DOSAGE')
	1FFC-1FFD	SWI	- 1B00 ('MINUTE')
	1FFE-1FFF	RESET	- 1800 ('RESET')

## MAIN ROUTINES:

## (RESET SWITCH)

## (146805 PORT SET-UP)

	1000 1800	RESET	A6FC	LDA	#\$FC	INITIALIZE 146805E2
5	1002 1802		B704	STA	0004	PORT A DDR SET, PA0 & PA1 INPUTS
	1004 1804		A6FF	LDA	#\$FF	
	1006 1806		B705	STA	0005	PORT B DDR SET, ALL OUTPUTS
10	1008 1808		A6E3	LDA	#\$E3	
	100A 180A		B700	STA	0000	PORT A OUTPUTS INACTIVE
	100C 180C		A640	LDA	#\$40	
15	100E 180E		B701	STA	0001	PORT B OUTPUTS TURNED OFF
	1010 1810		CC1820	JMP	RECOGN	
			[19]			
20	NOTE: 146818 DOES NOT NEED TO BE INITIALIZED AT THIS POINT ALTHOUGH NOT KEEPING CORRECT TIME, IT IS PROVIDING PROPER F2 (32.768 kHz) SIGNAL INTO 146805 FOR ACCURATE 110 BAUD TIMING UPON RESET: PIE,AIE,UIE,SQWE ARE CLEARED IRQF,PF,AF,UF ARE CLEARED					

**(LOAD/UNLOAD RECOGNITION)**

1020 1820 RECOGN A652 LDA #52  
1022 1822 CD1E00 JSR SEND C SENDS 'R'(\$52)  
FOR 'READY'

5	1025 1825	CD1E40 JSR	REC C	WAITING TO RECEIVE 'L' OR 'U'
	1028 1828	A155 CMP	#\$55	CHECK FOR 'U' (UNLOAD)
	102A 182A	2603 BNE	RECOG1	
	102C 182C	CC1900 JMP	UNLOAD	
10	102F 182F	RECOG1	A14C CMP	#\$4C CHECK FOR 'L' (LOAD)
	1031 1831	2603 BNE	RECOG2	
	1033 1833	CC1840 JMP	LOAD	
	1036 1836	RECOG2	CC1E80 JMP	BADCOM TO 'BAD COMMUNICATION' IF NOT 'U', 'L'

15 [25]

(LOAD DATA FROM BASE UNIT)

1040 1840	LOAD	A64C	LDA	#\$4C
1042 1842		CD1E00	JSR	SEND C SEND 'L' (LOAD ECHO)

1045 1845 LOAD1 CD1E40 JSR REC.C WAITING TO RECEIVE  
`C'(CONTINUE)

20 1048 1848 A143 CMP #\\$43 CHECK FOR 'C'  
104A 184A 26E9 BNE LOAD1 LOOP (INTELL. 'C')

104C 184C	A652	LDA	#\$52
104E 184E	CD1E00	JSR	SEND_C SEND_R (READY)

## (RECEIVE/STORE/ECHO LOOP)

1051 1851	5F	CLR	X	
1052 1852	LOAD2	CD1E40	JSR	REC C WAITING FOR DATA
1055 1855		D7010E	STA	X,010E WRITE DATA INTO RTC
5				RAM STARTING AT 010E
1058 1858	4F	CLR	A	
1059 1859		D6010E	LDA	X,010E RELOAD A FROM RTC FOR
		ECHO		
105C 185C		CD1E00	JSR	SEND C ECHO
10	105F 185F	5C	INC	X INCREMENT RTC MEMORY
				POINTER
1060 1860	A332	CPX	#\$32	CHECK FOR END OF FILE
				(50 ITEMS)
1062 1862	26EE	BNE	LOAD2	LOOP FOR NEXT DATA

## 15 BELL TEST - SOLENOID TEST)

1064 1864	LOAD4	CD1E40	JSR	REC C WAITING FOR 'C' OR 'B'
				OR 'U'
1067 1867	A143	CMP	#\$43	CHECK FOR 'C'
				(COMPLETE)
20 1069 1869	2712	BEQ	LOAD3	
106B 186B	A142	CMP	#\$42	CHECK FOR 'B' (BELL)
106D 186D	2605	BNE	LOAD5	
106F 186F		CD1EA2	JSR	BELL RING BELL
1072 1872	20F0	BRA	LOAD4	
25 1074 1874	LOAD5	A155	CMP	#\$55 CHECK FOR 'U' (UNLOCK)
1076 1876	26EC	BNE	LOAD4	
1078 1878		CD1E90	JSR	UNLOCK PULSE UNLOCK SOLENOID
107B 187B	20E7	BRA	LOAD4	

107D 187D	LOAD3	A646	LDA	#\$46
107F 187F		CD1E00	JSR	SEND C SEND 'F' TO ACKNOWLEDGE FINISH
1082 1882		CC18A0	JMP	START
5		[69]		

---

(INITIALIZE 146818 RTC)					
10A0 18A0	START	A6A6	LDA	#\$A6	
10A2 18A2		C7010B	STA	010B	RTC PUT ON HOLD DURING TIME SET
10 10A5 18A5		4F	CLR	A	
10A6 18A6		C70100	STA	0100	SECONDS SET TO 00
10A9 18A9		A63B	LDA	#59	
10AB 18AB		C70101	STA	0101	SECONDS ALARM SET FOR 59
15 10AE 18AE		A6FF	LDA	#\$FF	DONT CARE CODE
10B0 18B0		C70103	STA	0103	MINUTES ALARM SET
10B3 18B3		C70105	STA	0105	HOURS ALARM SET
10B6 18B6		A62A	LDA	#\$2A	SET RTC REGISTER A
10B8 18B8		C7010A	STA	010A	32.768 kHz, 15.625 mSec
20		PI, 64 Hz SQW			
10BB 18BB		C60138	LDA	0138	READ STARTING MINUTES
10BE 18BE		C70102	STA	0102	STARTING MINUTES MOVED INTO 0102
10C1 18C1		C60139	LDA	0139	READ STARTING HOURS
25 10C4 18C4		C70104	STA	0104	STARTING HOURS MOVED INTO 0104
10C7 18C7		A607	LDA	#7	
10C9 18C9		C70106	STA	0106	DAY OF WEEK SET TO 7

---

## (INITIALIZE 146805 RAM REGISTERS)

10CC 18CC	B71A	STA	DAYWEK	DAY OF WEEK REFERENCE SET TO 7
10CE 18CE	C6011F	LDA	011F	D1
5 10D1 18D1	B715	STA	NEXTHR	FIRST DOSAGE POINTER INTO NEXTHR
10D3 18D3	3F16	CLR	DAYCNT	
10D5 18D5	3C16	INC	DAYCNT	ACTUAL DAY COUNTER SET TO 1
10 10D7 18D7	C6013A	LDA	013A	
10DA 18DA	B717	STA	@DAY	
10DC 18DC	3C17	INC	@DAY	LOAD TARGET DAY WITH OFFSET + 1
10DE 18DE	3F1C	CLR	DOSTKN	CLEAR DOSES TAKEN COUNTER
15 10E0 18E0	1F00	BCLR7	PA7	ENABLE MICROSWITCH #1

## (INITIALIZE @HOUR &amp; @HOUR2 &amp; SET CLOCK)

10E2 18E2	CD1ECD	JSR	ADVTG1	SET 1st DOSE TIME INTO DISPLAY
-----------	--------	-----	--------	-----------------------------------

## 20 (CLEAR DOSAGE MEMORY)

10E5 18E5	5F	CLR	ACCX	
10E6 18E6	START1	6F1D	CLR	001D,X CLEAR 80 BYTES STARTING @ 001D
10E8 18E8	5C	INC	ACCX	PREVENTS ACCIDENTAL \$1A (26) IN
25 10E9 18E9	A350	CPX	#80	UNUSED BYTES
10EB 18EB	26F9	BNE	START1	

## (146805 TIMER SETUP)

10ED 18ED      A630 LDA \$30      SET UP TIMER CONTROL  
                  REGISTER  
10EF 18EF      B709 STA TCR      TCR7 - INTERRUPT  
5                                    REQUEST CLEARED  
                  TCR6 - INTERRUPT MASK  
                  CLEARED  
                  TCR5 - EXTERNAL CLOCK  
                  SOURCE  
10                                    TCR4 - EXTERNAL TIMER  
                  PIN ENAB.  
                  TCR3 - PRESCALER NOT  
                  RESET TO 0  
                  TCR2 - TCR0 DIVIDE BY 1

---

## 15                                    (LET RTC RUN)

10F1 18F1      C6010C LDA 010C      READING REGISTER C  
                  CLEAR ALARM FLAG  
10F4 18F4      A626 LDA #\\$26      SET RTC REGISTER B  
10F6 18FE      C7010B STA 010B      RUN, AIE ON, PIE, UIE,  
20                                    SQWE OFF BINARY,  
                  24, NO DSE

---

10F9 18F9      CC1B00 JMP MINUTE      GO TO 'MINUTE' TO SET  
                  BELL & UNLOCK

---

[ ]

---

## (UNLOAD DATA TO BASE UNIT)

## (HANDSHAKE COMMUNICATIONS)

1100 1900 UNLOAD A655 LDA \$55  
1102 1902 CD1E00 JSR SEND C SEND 'U' (UNLOAD  
5 ECHO)  
1105 1905 ULOAD1 CD1E40 JSR REC C WAITING TO RECEIVE  
'C' (CONTINUE)  
1108 1908 A143 CMP 43 CHECK FOR 'C'  
110A 190A 26F9 BNE ULOAD1 LOOP UNTIL 'C'

---

## 10 (146818 USER RAM UNLOAD/ECHO CHECK LOOP)

110C 190C 5F CLR X  
110D 190D ULOAD2 D6010E LDA 010E,X MOVE CHARACTER FROM  
RTC RAM INTO A  
1110 1910 AD12 BSR ULOAD6  
15 1112 1912 5C INC X INCREMENT DATA COUNTER  
1113 1913 A332 CPX 50  
1115 1915 26F6 BNE ULOAD2 REPEAT LOOP UNTIL  
50 BYTES

---

## (146805 UNLOAD/ECHO CHECK LOOP)

1117 1917	5F	CLR	X	
1118 1918	ULOAD4	E61C	LDA	001C,X LOAD DOSAGE DELIVERY DATA
5 111A 191A		AD08	BSR	ULOAD6 SEND DATA & CHECK ECHO
111C 191C		5C	INC	X INCREMENT DATA COUNTER
111D 191D		A351	CMP	#81 TEST FOR 81 BYTES SENT
10 111F 191F		26F7	BNE	ULOAD4 REPEAT LOOP UNTIL 81 BYTES
1121 1921		CC1A00	JMP	WAIT WAIT FOR INTERRUPT OR RESET EXTERNAL INTERRUPTS ENABLED POWER DOWN

## (SEND DATA/CHECK ECHO SUBROUTINE)

1124 1924	ULOAD6	CD1E00	JSR	SEND C
1127 1927		CD1E40	JSR	REC C WAITING FOR ECHO
20 112A 192A		B110	CMP	0010,A CHECK FOR PROPER ECHO
112C 192C		2703	BEQ	ULOAD3
112E 192E		CC1E80	JMP	BADCOM BAD ECHO, GO TO 'BAD COMMUNICATION'
1131 1931	ULOAD3	81	RTS	

25 [50]

(POWER DOWN MODE - WAITING FOR INTERRUPTS)

1200 1A00 WAIT 8F WAIT WAIT FOR INTERRUPT OR  
RESET EXTERNAL  
INTERRUPTS ENABLED  
5 POWER DOWN

[1]

---

TIMER INTERRUPT

(RTC ALARM - 1/MIN)

(INTERRUPT MASK BIT SET AUTOMATICALLY UPON INTERRUPT)

10 (ALLOW ONLY EXTERNAL INTERRUPTS)

1300 1B00 MINUTE 1C09 BSET6 TCR6 (5) MASK TIMER  
INTERRUPTS  
1302 1B02 9D NOP ( )  
1303 1B03 9C RSP ( ) DON'T USE UP  
15 STACK  
1304 1B04 9A CLI (2) ALLOW EXTERNAL  
INTERRUPTS

-----  
(12) 1.8 mSec

---

20 (TIMER INTERRUPT INDICATOR - FOR DEBUG ONLY)

1305 1B05 MINUT1 1400 BSET2 PA2 TURN ON GREEN LED -  
TIMER INT. INDIC.

---

(UPDATE HOURS, MINUTES, AND DAY)

1307 1B07 CD1F30 JSR RTCRED ACTUAL HOURS IN 0018  
('HOURS')

5 ACTUAL MINUTES IN  
0019 ('MINUTS')  
DAY OF WEEK IN 001C  
('ATEMP')

130A 1B0A	B610	LDA	ATEMP	CURRENT DAY OF WEEK
130C 1B0C	B11A	CMP	DAYWEK	HAS DAY OF WEEK
10				CHANGED?
130E 1B0E	2704	BEQ	BELLOK	
1310 1B10	B71A	STA	DAYWEK	UPDATE DAY OF WEEK
				REFERENCE
1312 1B12	3C16	INC	DAYCNT	UPDATE ACTUAL DAYS
15				COUNT

**(ACTUAL VS TARGET TIME TESTS)**

1314 1B14	BELLOK	B617	LDA	@DAY
1316 1B16		4C	INC	ACCA
1317 1B17		B116	CMP	DAYCNT IS TD+1 < AD ?
20 1319 1B19		2406	BHS	MINUT2
		(AD > TD + 1)		
131B 1B1B		CD13C0	JSR	ADVTGT VERY LATE - ADVANCE
				TARGET

```

25  131E 1B1E          CC1B14 JMP    BELLOK  RESTART
    1321 1B21  MINUT2  2620  BNE    MINUT3
                      (AD = TD + 1)
    1323 1B23          B618   LDA    HOURS
    1325 1B25          AB18   ADD    #24
30  1327 1B27          B111   CMP    0011  IS HOURS + 24 >=
                      @HOUR2 - 1

```

## (ACTUAL VS TARGET TIME TESTS, continued)

1329 1B29	2506	BLO	MINUT4	
132B 1B2B	CD1EC0	JSR	ADVTGT	VERY LATE - ADVANCE
				TARGET
5 132E 1B2E	CC1B14	JMP	BELLOK	RESTART
1331 1B31	MINUT4	CD1E90	JSR	UNLOCK LATE ALL - UNLOCK IF
				LOCKED & RING BELL
1334 1B34	MINT11	CD1EA2	JSR	BELL RING BELL FOUR TIMES
1337 1B37		CD1EA2	JSR	BELL
10 133A 1B3A		CD1EA2	JSR	BELL
133D 1B3D		CD1EA2	JSR	BELL
1340 1B40		CC1B95	JMP	MINT15 EXIT
1343 1B43	MINUT3	B616	LDA	DAYCNT
1345 1B45		B117	CMP	@DAY
15 1347 1B47		252F	BLO	MINUT5
		(ACTUAL DAY = TARGET DAY)		
1349 1B49		B618	LDA	HOURS
134B 1B4B		B111	CMP	0011 IS HOURS < @HOUR2 - 1?
134D 1B4D		2506	BLO	MINUT6
20 134F 1B4F		CD1EC0	JSR	ADVTGT
				VERY LATE - ADVANCE
				TARGET
1352 1B52		CC1B14	JMP	BELLOK
1355 1B55	MINUT6	B114	CMP	RESTART @HOUR
1357 1B57		2503	BLO	MINUT7
25 1359 1B59		CC1B31	JMP	MINUT4 LATE - UNLOCK & RING
				BELL
135C 1B5C	MINUT7	4C	INC	ACCA
135D 1B5D		B114	CMP	@HOUR DOES HOURS=@HOUR - 1?
135F 1B5F		2611	BNE	MINUT8
30		(WITHIN 1 HOUR)		
1361 1B61	MINT14	B619	LDA	MINUTS
1363 1B63		C10126	CMP	0126 CHECK UNLOCK PERIOD
1366 1B66		2505	BLO	MINUT9

## (ACTUAL VS. TARGET TIME TESTS, continued)

	1368 1B68	CD1E90 JSR	UNLOCK	UNLOCK IF NECESSARY	
				(AM >= UP)	
	136B 1B6B	B619 LDA	MINUTS		
5	136D 1B6D	MINUT9 C10127 CMP	0127	CHECK ALARM PERIOD	
	1370 1B70	2403 BHS	MINT10		
	1372 1B72	MINUT8 CC1B95 JMP	MINT15	EARLY - EXIT	
	1375 1B75	MINT10 CC1B34 JMP	MINT11	RING BELL & EXIT	
				(AM >= AP)	
<hr/>					
10	1378 1B78	MINUTS 4C INC	ACCA	DAYCNT + 1	
	1379 1B79	B117 CMP @DAY		DOES AD = TD - 1 ?	
	137B 1B7B	2613 BNE	MINT12		
				(AD = TD -1)	
	137D 1B7D	3D14 TST @HOUR			
15	137F 1B7F	2609 BNE	MINT13		
				(@HOUR = 0)	
	1381 1B81	B618 LDA	HOURS		
	1383 1B83	A117 CMP #23			
	1385 1B85	2603 BNE	MINT13		
20				(AH = 23)	
	1387 1B87	CC1B61 JMP	MINT14	GO TO WITHIN 1 HOUR	
				TESTS	
	138A 1B8A	MINT13 B618 LDA	HOURS		
	138C 1B8C	B114 CMP @HOUR			
25	138E 1B8E	2208 BHI	MINT16	<24 HOURS EARLY -	
				EXIT	
	1390 1B90	MINT12 CD1F80 JSR	DASH	>24 HOURS EARLY -	
				DISPLAY DASH	
	1393 1B93	2003 BRA	MINT16	EXIT WITHOUT	
30				DISTURBING DASH	

## (ACTUAL VS TARGET TIME TESTS, continued)

1395 1B95	MINT15	CD1EEB JSR	CLKADV	UPDATE CLOCK TO CLEAR OBSOLETE DASH
1398 1B98	MINT16	C6010C LDA	010C	READ RTC REG C TO CLEAR ALARM FLAG
5				
139B 1B9B		A601 LDA	#\$01	
139D 1B9D		B708 STA	T1DATA	LOAD TIMER WITH ONE COUNT
139F 1B9F		1F09 BCLR7 TCR7		CLEAR TIMER INTERRUPT REQUEST
10				
13A1 1BA1		1D09 BCLR6 TCR6		ALLOW TIMER INTERRUPTS
<hr/>				
13A3 1BA3		1500 BCLR2 PA2		TURN OFF GREEN LED - TIMER INT. INDIC.
<hr/>				
13A5 1BA5		CC1A00 JMP	WAIT	BACK TO 'WAIT'
<hr/>				
15		[ ]		
<hr/>				
EXTERNAL INTERRUPT				
(DOSAGE TAKEN - ACTIVE MICROSWITCH ACTUATION)				
(INTERRUPT MASK BIT SET AUTOMATICALLY UPON INTERRUPT)				
(EXTERNAL INTERRUPT INDICATOR - FOR DEBUG ONLY)				
20	1500 1D00	DOSAGE 1600	BSET3 PA3	(5) LIGHT RED LED - EXT. INT. INDIC.
<hr/>				

**(INTERCHANGE INTERRUPT SWITCH ACTIVATION)**

1502 1D02	B600	LDA	PORTA	(3)
1504 1D04	A8C0	EOR	#\$C0	(2) 1100 0000
1506 1D06	B700	STA	PORTA	(4) PA7 & PA6 STATES CHANGED

5 : **CHANGED**

(READ/PACK/STORE DATA)

1508 1D08	CD1F30 JSR	RTCRED	(6) GET CURRENT HOUR, MINUTE, DAY DATA
1508 1D0B	3C1C INC	DOSTKN	(5) INCREMENT DOSES TAKEN COUNTER
150D 1D0D	CD1F50 JSR	PACK	(6) PACK/STORE DAY & TIME DATA

10 TAKEN COUNTER  
150D 1D0D CD1F50 JSR PACK (6) PACK/STORE DAY &  
TIME DATA

(CHECK FOR UNIT EMPTY)

1510 1D10	B61C	LDA	DOSTKN	( )
15 1512 1D12	C1013B	CMP	013B	( ) TEST AGAINST
				TOTAL # OF
				DOSAGES, TD
1515 1D15	2508	BLO	DOSAG1	( )
1517 1D17	CD1F80	JSR	DASH	DISPLAY DASH
20 151A 1D1A	1E00	BSET7	PA7	MICROSWITCHES
DEACTIVATED - NO EXT. INT				
151C 1D1C	1C00	BSET6	PA6	
151E 1D1E	8E	STOP		WAIT FOR RESET -
				POWER DOWN

25 (ADVANCE TARGET REGISTERS & UPDATE DISPLAY)

151F 1D1F DOSAG1 CD1EC0 JSR ADVTGT ( ) ADVANCE TARGETS

1522 1D22 1700 BCLR3 PA3 ( ) RED LED OFF

(EXIT TO MINUTE FOR BELL AND UNLOCK CHECK &amp; THEN WAIT)

1524 1D24 CC1B00 JMP MINUTE

[ ]

## 5 SUBROUTINES:

(SERIAL OUTPUT CHARACTER MUST BE IN A)

(USES REG A, REG X, 0010, 0011, 0012)

(ALTERS A, RESTORES X, CHARACTER IN 0010)

1600 1E00 SEND C BF13 STX XTEMP (4) STORE X FOR LATER  
 10 RESTORATION

1602 1E02 B710 STA ATEMP (4)

1604 1E04 B711 STA CHAR (4) STORE CHARACTER  
 IN 0010 FOR ECHO  
 CHECK & IN 0011  
 FOR SENDING

1606 1E06 A609 LDA #9 (2) OUTPUT 9 BITS  
 (8 + START)

1608 1E08 B712 STA COUNT (4) BIT COUNTER IN  
 0012

20 160A 1E0A 2008 BRA SENDC3 (3) BRANCH TO OUTPUT  
 A 0 (START BIT)

(21)

25 160C 1E0C SENDC2 3611 ROR CHAR (5) MOVE NEXT BIT  
 INTO CARRY

160E 1E0E SENDC1 2404 BCC SENDC3 (3) TEST FOR SET OR  
 CLEAR BIT

1610 1E10 1A00 BSETS PAS OUTPUT A 1

1612 1E12 2004 BRA SENDC4 BRANCH TO DELAY

1614 1E14	SEND C3	1B00	BCLR5	PA5	(5) OUTPUT A 0
1616 1E16		2000	BRA	SEND C4	(3) EQUALIZE TIMING
1618 1E18	SEND C4	CD1E30	JSR	DELAY	(6) TO TIMING DELAY FOR 110 BAUD
5 161B 1E1B		3A12	DEC	COUNT	(5) DECREMENT BIT COUNTER
161D 1E1D		26ED	BNE	SEND C2	(3) TEST IF ANOTHER BIT TO SEND
10					(60) CYCLES BETWEEN BITS
-----					
161F 1E1F	STOPBT	9D	NOP		(2) 8 CYCLE DELAY
1620 1E20		9D	NOP		(2)
1621 1E21		9D	NOP		(2)
15 1622 1E22		9D	NOP		(2)
1623 1E23		1A00	BSET5	PA5	(5) SEND STOP BIT
1625 1E25		CD1E30	JSR	DELAY	(6) DELAY FOR THE STOP BIT
-----					
1628 1E28		BE13	LDX	0013	(3) RESTORE X
20 162A 1E2A		81	RTS		(6) RETURN
		[43]			ASSUMES 8 CYCLES TO REENTER SEND C (129 CYCLES BETWEEN CHARACTERS)
-----					
25					

## 30 CYCLE (4.58 mSec) DELAY FOR SEND/RECEIVE SUBROUTINES

(ALTERS X UNLESS USED BY SEND C OR REC C)

1630 1E30    DELAY    AE03    LDX    #\$03    (2) COUNTER SET TO 3

5    1632 1E32    DELAY1    5A    DECX    X    (3) DECREMENT LOOP  
COUNTER

1633 1E33    26FD    BNE    DELAY1    (3) LOOP

1635 1E35    9D    NOP    (2) EQUALIZATION

1636 1E36    9D    NOP    (2) EQUALIZATION

10    1637 1E37    81    RTS    (6) RETURN TO SEND C  
OR REC C

[8]

(30)  $2+3*6+10 = 30$ 

## (SERIAL INPUT CHARACTER GOES INTO A)

15    (ALTERS A, RESTORES X)

1640 1E40    REC C    BF13    STX    XTEMP    STORE REG X FOR LATER  
RESTORATION

1642 1E42    A608    LDA    #8

1644 1E44    B712    STA    COUNT    NUMBER OF DATA BITS  
TO READ20    1646 1E46    REC C1    0000FD BRSET REC C1    TESTS FOR HI TO LO  
START BIT  
TRANSITION ON PA0

1649 1E49 1/2DLY AE04 LDX #04 (2) DELAY 1/2 BIT  
TIME (30 CYCLES)  
164B 1E4B DLY1 5A DECX X (3) DECREMENT COUNTER  
164C 1E4C 26FD BNE DLY1 (3) LOOP  
5 164E 1E4E 9D NOP (2) TIMING  
EQUALIZATION  
164F 1E4F 9D NOP (2) " "  
—  
(30)

10

(NOW IN MIDDLE OF START BIT)  
1650 1E50 FALSE 0000F3 BRSET REC C1 (5) FALSE START BIT  
TEST  
1653 1E53 9D NOP (2) TIMING  
15 EQUALIZATION  
1654 1E54 9D NOP (2) " "  
1655 1E55 9D NOP (2) " "  
1656 1E56 9D NOP (2) " "  
1657 1E57 9D NOP (2) " "  
20 1658 1E58 2000 BRA REC C2 (3) " "  
—  
(18)

## (MAIN RECEIVE ROUTINE)

165A 1E5A	REC C2	CD1E30 JSR	DELAY	(6) ONE BIT TIMING DELAY
5 165D 1E5D		9D	NOP	(2) 6 CYCLE EQUALIZATION
165E 1E5E		9D	NOP	(2)
165F 1E5F		9D	NOP	(2)
1660 1E60		010000	BRCLR REC C3	(5) TEST INPUT (PA0) AND SET C-BIT
10 1663 1E63	REC C3	3611	ROR CHAR	(5) ASSEMBLE CHARACTER
1665 1E65		3A12	DEC COUNT	(5) DECREMENT BIT COUNTER
1667 1E67		26F1	BNE REC C2	(3) TEST FOR MORE BITS TO READ

(60) CYCLES BETWEEN  
BITS

---

20 1669 1E69	CD1E30 JSR	DELAY	WAIT OUT THE 9TH (STOP) BIT
--------------	------------	-------	--------------------------------

---

166C 1E6C	B611	LDA CHAR	PUT ASSEMBLED BYTE INTO A
25 166E 1E6E	BE13	LDX 0013	RESTORE X
1670 1E70	81	RTS	RETURN

---

[49]

(BAD COMMUNICATION - SENDS ASCII 30 AND WAITS)

1680 1E80 BADCOM 9C RSP RESET STACK POINTER  
 1681 1E81 A61E LDA #\$1E ASCII 30  
 1683 1E83 CD1E00 JSR SEND C SEND ASCII 30 (BAD  
 5 COMMUNICATION)  
 1686 1E86 C11A00 JMP WAIT WAIT FOR RESTART  
 --- (RESET WILL RESET SP  
 TO 7F)

[9]

10

(UNLOCK SOLENOID ON FOR 50 mSec)

(ALTERS A, ALTERS X)

(TEST UNLOCK SWITCH)

1690 1E90 UNLOCK 020001 BRSET1UNLCK1 IS SPROCKET LOCKED ?  
 15 (PA1 = 1)  
 1693 1E93 81 RTS EXIT - ALREADY  
 UNLOCKED

20

1694 1E94 UNLCK1 1800 BSET4 PA4 TURN ON UNLOCK  
 SOLENOID

25 30

1696 1E96 A60B LDA #11 11\*4.58=50 mSec  
 ON DELAY

1698 1E98 UNLCK2 CD1E30 JSR DELAY

169B 1E9B 4A DEC A

169C 1E9C 26FA BNE UNLCK2 LOOP

169E 1E9E 1900 BCLR4 PA4 TURN OFF UNLOCK  
 SOLENOID

16A0 1EA0 81 RTS

[17]

(PIEZO ALARM ON FOR 100 mSec / OFF FOR 500 mSec)

(ALTERS X, ALTERS A)

16A2 1EA2 BELL 1E01 BSET7 PB7 BELL ON

5 16A4 1EA4 A610 LDA #16 ON DELAY OF 6.4 \* 16  
= 100 mSec

16A6 1EA6 BELL01 CD1E30 JSR DELAY

16A9 1EA9 4A DEC A

16AA 1EAA 26FA BNE BELL01

10

16AC 1EAC 1F01 BCLR7 PB7 BELL OFF

16AE 1EAE A650 LDA #80 500 mSec OFF DELAY

16B0 1EB0 BELL02 CD1E30 JSR DELAY

15 16B3 1EB3 4A DEC A

16B4 1EB4 26FA BNE BELL02

16B6 1EB6 81 RTS

20

[21]

(INCREMENT 'NEXTHR', '@DAY' IF NECESSARY)

(UPDATE '@HOUR' &amp; '@HOUR2' &amp; DISPLAY)

16C0 1EC0 ADVTGT 3C15 INC NEXTHR INCREMENT NEXT HOUR  
 POINTER

5

---

16C2 1EC2	B615	LDA	NEXTHR
16C4 1EC4	C1011A	CMP	011A COMPARE AGAINST SN
16C7 1EC7	2504	BLO	ADVTG1
16C9 1EC9	3F15	CLR	NEXTHR WRAP NEXT HOUR
10			POINTER TO 0
16CB 1ECB	3C17	INC	@DAY INCREMENT TARGET DAY
			COUNTER
16CD 1ECD	ADVTG1	BE15	LDX NEXTHR
16CF 1ECF		D6011B	LDA 011B,X
15 16D2 1ED2		B714	STA @HOUR UPDATE TARGET HOUR
			REGISTER

---

(DETERMINE UPCOMING TARGET HOUR)

16D4 1ED4	5C	INC	ACCX
20 16D5 1ED5	C3011A	CPX	011A COMPARE AGAINST SN
16D8 1ED8	2507	BLO	ADVTG2
16DA 1EDA	C6011B	LDA	011B SC(0)
16DD 1EDD	AB18	ADD	#24 +24 IF NEXT DAY
16DF 1EDF	2003	BRA	ADVTG3
25 16E1 1EE1	ADVTG2	D6011B	LDA 011B,X
16E4 1EE4	ADVTG3	B71B	STA @HOUR2 UPDATE UPCOMING
			TARGET HOUR
16E6 1EE6	B61B	LDA	@HOUR2
16E8 1EE8	4A	DEC	ACCA
30 16E9 1EE9	B711	STA	0011 @HOUR2 - 1 INTO
			'CHAR'

---

## (LCD UPDATE TO NEXT DOSING HOUR)

## (AM/PM CHECK)

	16EB 1EEB	CLKADV	B614	LDA	@HOUR	
	16ED 1EED		A10B	CMP	#11	TEST FOR AM OR PM
5	16EF 1EEF		2204	BHI	PM	
	16F1 1EF1		A630	LDA	#\$30	AM
	16F3 1EF3		2002	BRA	CLK1	
	16F5 1EF5	PM	A632	LDA	#\$32	PM
	16F7 1EF7	CLK1	CD1F25	JSR	LCDOUT	DIGIT 1 UPDATED
10						(CONVERT FROM 24 TO 12 HOUR)
	16FA 1EFA		B614	LDA	@HOUR	
	16FC 1EFC		4D	TST	ACCA	
	16FD 1EFD		2604	BNE	CLK2	
	16FF 1EFF		AB0C	ADD	#12	0 CONVERTED TO 12
15	1701 1F01		2006	BRA	CLK3	
	1703 1F03	CLK2	A10C	CMP	#12	
	1705 1F05		2302	BLS	CLK3	
	1707 1F07		A00C	SUB	#12	13-23 CONVERTED TO 1-11
						(HOUR SEPARATED INTO ONES AND TENS DIGITS)
20	1709 1F09	CLK3	A10A	CMP	#10	
	170B 1F0B		250D	BLO	CLK4	
	170D 1F0D		A00A	SUB	#10	
	170F 1F0F		AB10	ADD	#16	DS1=1 DS2=0
	1711 1F11		CD1F25	JSR	LCDOUT	DIGIT 3 LOADED WITH
25						0,1, OR 2
	1714 1F14		A601	LDA	#01	
	1716 1F16		CD1F25	JSR	LCDOUT	DIGIT 4 LOADED WITH 1
	1719 1F19		81	RTS		EXIT
	171A 1F1A	CLK4	AB10	ADD	#16	
30	171C 1F1C		CD1F25	JSR	LCDOUT	DIGIT 3 LOADED WITH
						0-9
	171F 1F1F		A60F	LDA	#\$0F	
	1721 1F21		CD1F25	JSR	LCDOUT	DIGIT 4 BLANKED
	1724 1F24		81	RTS		EXIT
35			[ ]			

## (LOAD DISPLAY DIGIT)

1725 1F25	LCDOUT	B701	STA	PORT B	DIGIT & DS1,DS2 DATA	
						TO 7211
5	1727 1F27	1D01	BCLR6	PB6	CHIP SELECTS GO LOW	
					(LATCH INPUT)	
10	1729 1F29	1C01	BSET6	PB6	CHIP SELECTS GO HI	
					(LATCH OUTPUT)	
	172B 1F2B	81	RTS			
		-----				
		[ ]				

---

## (READ RTC HOURS &amp; MINUTES)

1730 1F30	RTCRED	C6010C	LDA	010C	(4) READING RTC REG C	
					CLEAR'S PF BIT	
15	1733 1F33	RTCRD1	C6010C	LDA	010C	(4) (4) (4) LOAD REG
					C FOR TESTING	
20	1736 1F36	A440	AND	#\$40	(2) (2) (2) LOOKING	
					FOR BIT 6 (PF)	
					HIGH	
25	1738 1F38	27F9	BEQ	RTCRD1	(3) (3) (3) LOOP IF	
					PF NOT SET	
	173A 1F3A	C60104	LDA	0104	(4) (4) LOAD CURRENT	
					HOURS	
	173D 1F3D	B718	STA	HOURS	(4) (4) STORE (000H	
					HHHH) IN 'HOURS'	
30	173F 1E3F	C60102	LDA	0102	(4) (4) LOAD CURRENT	
					MINUTES	
	1742 1F42	B719	STA	MINUTS	(4) STORE (00MM MMMM)	
					IN 'MINUTS'	

---

1744 1F44	C60106	LDA	0106	(4) LOAD DAY OF WEEK
1747 1F47	B710	STA	ATEMP	STORE IN 'ATEMP'
1749 1F49	81	RTS		(6)

5	[ ]	( )+( ) = mSec
		MINIMUM VALID
		ACCESS TIME
		REQUIRED
		7.5 mSec (1/2 PI)
10		IS AVAILABLE

## (PACK DATA INTO TWO BYTES &amp; STORE)

1750 1F50	PACK	3419	LSR	MINUTS (5) DIVIDES MINUTES BY 2 (000M MMMM)
-----------	------	------	-----	--

1752 1F52	BE1C	LDX	DOSCNT (3) LOAD X WITH MEMORY POINTER
-----------	------	-----	--

1754 1F54	58	LSL	X (3) MULTIPLY MEMORY POINTER X2
-----------	----	-----	-------------------------------------

1755 1F55	B616	LDA	DAYCNT (3) (00DD DDDD)
-----------	------	-----	------------------------

1757 1F57	48	LSL	A (3)
-----------	----	-----	-------

20 1758 1F58	48	LSL	A (3) (DDDD DD00)
--------------	----	-----	-------------------

1759 1F59	A4E0	AND	#\$E0 (2) (DD00 0000) DAYS HI
-----------	------	-----	----------------------------------

175B 1F5B	BB19	ADD	MINUTS (3) (DDDM MMMM) DAYS HI + MINUTES
-----------	------	-----	---

25 175D 1F5D	A11A	CMP	#26 (2) CHECK FOR BREAK CODE
--------------	------	-----	---------------------------------

175F 1F5F	2602	BNE	PACK1 (3) OK
-----------	------	-----	--------------

1761 1F61	A61F	LDA	#31 (2) CHANGE 26 TO 31
-----------	------	-----	-------------------------

1763 1F63	PACK1	E71C	STA 001C,X (6) PACKED DATA STORED IN 146805 RAM
-----------	-------	------	--

1765 1F65	B616	LDA	DAYCNT	(3) (00DD DDDD)
1767 1F67	48	LSL	A	(3)
1768 1F68	48	LSL	A	(3)
1769 1F69	48	LSL	A	(3)
5 176A 1F6A	48	LSL	A	(3)
176B 1F6B	48	LSL	A	(3) (DDDD 0000)
				DAYS LO
176C 1F6C	BB18	ADD	HOURS	(3) (DDDH HHHH)
				DAYS LO + HOURS
10 176E 1F6E	A11A	CMP	#26	(2) CHECK FOR BREAK
				CODE
1770 1F70	2602	BNE	PACK2	(3) OK
1772 1F72	A61F	LDA	#31	(2) CHANGE 26 TO 31
1774 1F74	PACK2	E71B	STA	001B,X (6) PACKED DATA STORED
15				IN 146805 RAM
1776 1F76	81	RTS		(6)
				[ ] ( ) = mSec
20				

## (PUT DASH IN HOUR DISPLAY)

1780 1F80	DASH	A60F	LDA	#\$0F
1782 1F82		CD1F25	JSR	LCDOUT DIGIT 4 BLANKED
1785 1F85		A61A	LDA	#\$1A
25 1787 1F87		CD1F25	JSR	LCDOUT DIGIT 3 LOADED WITH
				A DASH
178A 1F8A		A630	LDA	#\$30
178C 1F8C		CD1F25	JSR	LCDOUT DIGIT 1 LOADED WITH
30 178F 1F8F		81	RTS	AN A
				[ ]

## IDENTIFYING ASCII

	17E0 1FE0	4D	M
	17E1 1FE1	4D	M
5	17E2 1FE2	53	S
	17E3 1FE3	40	@
	17E4 1FE4	30	0
	17E5 1FE5	38	8
	17E6 1FE6	2F	/
10	17E7 1FE7	32	2
	17E8 1FE8	32	2
	17E9 1FE9	2F	/
	17EA 1FEA	38	8
	17EB 1FEB	34	4

15

## INTERRUPT VECTORS:

	17F6 1FF6	1B00	TIMER INTERRUPT FROM WAIT - 1B00
20			('MINUTE')
	17F8 1FF8	1B00	TIMER INTERRUPT - 1B00 ('MINUTE')
	17FA 1FFA	1D00	EXTERNAL INTERRUPT - 1D00 ('DOSAGE')
25	17FC 1FFC	1B00	SWI - 1B00 ('MINUTE')
	17FE 1FFE	1800	RESET - 1800 ('RESET')

[10]

30

[ ]

CONTROLLED DISPENSING DEVICE  
"LOAD-M" PROGRAM LISTING

## APPENDIX II

```
10  REM      LOAD-M
5   20  REM      10/13/84
     30  REM      REV 04
     40  CLEAR
     50  MAXFILES=2
     90  ON ERROR GOTO 430
10  95  REM.-----LOGO-----
100 CLS:LINE (10,2)-(228,60),1,B:LINE (12,4)-(226,58),1,B
110 PRINT @47,"MEDICAL MICROSYSTEMS, INC."
120 PRINT @133,"Copyright 1984"
130 PRINT @248,"Monitor Loading Routine"
15  135 PRINT @275,"A4"
140 FOR I=1 TO 1000:NEXT I
145 REM -----ENTER DATA-----
150 CLS:LINE (184,30)-(221,41),1,B
160 PRINT @163,"";:LINE INPUT "ENTER STUDY ID.# (6 Digits)
20  ";SI$
161 LE=LEN(SI$):IF LE>6 THEN SI$=LEFT$(SI$,6)
162 IF LE<6 THEN 164 ELSE 170
164 FOR I=1 TO 6-LE:SI$=" "+SI$:NEXT I
170 CLS:LINE (190,30)-(227,41),1,B
25  180 PRINT @162,"";:LINE INPUT "ENTER PATIENT ID.#
     (6 DIGITS)      ";PI$
181 LF=LEN(PI$):IF LF>6 THEN PI$=LEFT$(PI$,6)
182 IF LF<6 THEN 184 ELSE 185
184 FOR I=1 TO 6-LF:PI$=" "+PI$:NEXT I
30  185 DIM SC(3),TI$(3),D$(49),IN(3)
190 SN=0:CLS:LINE (8,11)-(189,44),1,B
200 LINE (200,19)-(213,36),1,B:LINE(218,19)-(231,36),1,B
210 PRINT @1,"DAILY SCHEDULE SELECTION (1-4 Entries)"
```

```
220 PRINT @83,"1 AM 11 :1 PM 11"
230 PRINT @123,"212345678901 212345678901"
240 PRINT @154,"X":PRINT @157,"C"
250 PRINT @241,"Move cursor over hour and press 'ENTER'";
5 260 PRINT @286,"Restart - X Complete - C";
270 PRINT @122,"";
280 A$=INPUT$(1)
290 IF ASC(A$)=28 THEN PRINT @(120+POS(0)+1),"";
300 IF ASC(A$)=29 THEN PRINT @(120+POS(0)-1),"";
10 310 IF ASC(A$)<>13 THEN 280
320 IF CSRLIN<>3 THEN 280
330 IF POS(0)=34 THEN 190
340 IF POS(0)=37 THEN 440
350 IF POS(0)>29 OR POS(0)<3 THEN 280
15 360 IF POS(0)>14 AND POS(0)<18 THEN 280
370 IF POS(0)>14 THEN 390
380 SC(SN)=POS(0)-3:LA=SC(SN):IF LA=0 THEN LA=12
385 TI$(SN)=STR$(LA)+" AM":GOTO 393
390 SC(SN)=POS(0)-6:LA=SC(SN)-12:IF LA=0 THEN LA=12
20 392 TI$(SN)=STR$(LA)+" PM"
393 IF SN=0 THEN 395
394 IF SC(SN)<SC(SN-1) THEN 280
395 IF LA<10 THEN TI$(SN)=" "+TI$(SN)
400 IF LA>9 THEN LA=LA-10
25 405 L$=MID$(STR$(LA),2)
410 PRINT @(160+POS(0)),L$;:PRINT @(120+POS(0)),"";;
420 SN=SN+1:IF SN=4 THEN 460
425 GOTO 280
430 IF ERR=9 THEN RESUME 190
30 431 CLS:PRINT "ERROR":ERR:END
432 IF ERR=2 THEN RESUME 1200
434 PRINT "ERROR";:FOR I=1 TO 500:NEXT I:RESUME
440 IF SN=0 THEN 190
450 IF SN=1 THEN D1=0:GOTO 620
35 460 CLS:PRINT @8,"SELECT FIRST DOSAGE TIME";
```

```
470 FOR I=0 TO SN-1:PRINT @128+I*8, TI$(I);:NEXT I
480 PRINT @240, "Move box over first dosage & press ENTER";
490 LINE (3,20)-(39,36),1,B:PRINT @80,"";
500 A$=INPUT$(1):L1=POS(0)*6+3:L2=(POS(0)+6)*6+3
5 510 IF ASC(A$)<>28 THEN 550
520 IF (POS(0)-8)/8=SN-1 THEN 500
530 LINE (L1,20)-(L2,36),0,B:LINE(L1+48,20)-(L2+48,36),1,B
540 PRINT @88+POS(0),"":GOTO 500
550 IF ASC(A$)<>29 THEN 590
10 560 IF POS(0)<9 THEN 500
570 LINE(L1,20)-(L2,36),0,B:LINE(L1-48,20)-(L2-48,36),1,B
580 PRINT @72+POS(0),"":GOTO 500
590 IF ASC(A$)<>13 THEN 500
600 IF POS(0)=0 THEN 500
15 610 D1=(POS(0)-8)/8
620 CLS:PRINT @162,"":LINE INPUT "ENTER STARTING DAY OFFSET
      ";SD$
630 SD=VAL(SD$)
640 CLS:PRINT @162,"":LINE INPUT "ENTER # OF DOSES LOADED
20      (1-40) ";TD$
650 TD=VAL(TD$)
660 CLS:LINE(172,30)-(209,41),1,B
710 PRINT @166,"":LINE INPUT "ENTER MONITOR SERIAL # ";SN$
715 LG=LEN(SN$):IF LG>6 THEN SN$=LEFT$(SN$,6)
25 720 IF LG<6 THEN 730 ELSE 800
730 FOR I=1 TO 6-LG:SN$=SN$+SN$:NEXT I
800 I=1
801 IF I=7 THEN 805
802 IF MID$(SN$,I,1)=" " THEN I=I+1:GOTO 801
30 804 IF MID$(SN$,I,1)="L" THEN 810
805 UP$=" ALWAYS":UP=0:GOTO 1000
810 CLS:PRINT @10,"SELECT UNLOCK PERIOD";
820 PRINT @96," 2 Min.":CHR$(155);
830 PRINT @136," 30 Min.";
35 840 PRINT @176," 59 Min.":
```

```
850 PRINT @217,"Always";
860 PRINT @280,"Move arrow to selection and press
    ENTER";:PRINT @105,"";
870 A$=INPUT$(1)
5 880 IF ASC(A$)<>31 THEN 920
890 IF CSRLIN=5 THEN 870
900 GOSUB 910:PRINT @((CSRLIN+1)*40+24,CHR$(155));:GOTO 870
910 LINE (144,16)-(149,48),0,BF:RETURN
920 IF ASC(A$)<>30 THEN 950
10 930 IF CSRLIN=2 THEN 870
940 GOSUB 910:PRINT @((CSRLIN-1)*40+24,CHR$(155));:GOTO 870
950 IF ASC(A$)<>13 THEN 870
960 UP=CSRLIN-1
970 ON UP GOTO 972,974,976,978
15 972 UP$=" 2 Min.":UP=58:GOTO 1000
974 UP$=" 30 Min.":UP=30:GOTO 1000
976 UP$=" 59 Min.":UP=1:GOTO 1000
978 UP$=" ALWAYS":UP=61
1000 CLS:PRINT @11,"SELECT ALARM START";
20 1010 PRINT @97," 2 Min.":CHR$(155);
1020 PRINT @137,"15 Min.";
1030 PRINT @177,"30 Min.";
1040 PRINT @219,"NONE";
1050 PRINT @280,"Move arrow to selection and press
    ENTER";:PRINT @105,"";
25 1060 A$=INPUT$(1)
1070 IF ASC(A$)<>31 THEN 1100
1080 IF CSRLIN=5 THEN 1060
1090 GOSUB 910:PRINT @((CSRLIN+1)*40+24,CHR$(155));:GOTO 1060
30 1100 IF ASC(A$)<>30 THEN 1130
1110 IF CSRLIN=2 THEN 1060
1120 GOSUB 910:PRINT @((CSRLIN-1)*40+24,CHR$(155));:GOTO 1060
1130 IF ASC(A$)<>13 THEN 1060
1140 AP=CSRLIN-1
35 1150 ON AP GOTO 1160,1170,1180,1190
```

```

1160 AP$=" 2 Min.":AP=58:GOTO 1200
1170 AP$="15 Min.":AP=45:GOTO 1200
1180 AP$="30 Min.":AP=30:GOTO 1200
1190 AP$="  NONE":AP=61
5 1200 CLS:PRINT @48,"DATE IS: ";DATE$;
1210 PRINT @128,"TIME IS: ";TIME$;
1220 PRINT @205,"If correct press 'C'";
1230 PRINT @245,"If incorrect press 'I'";:PRINT @230,"";
1240 A$=INPUT$(1)
10 1250 IF ASC(A$)=67 THEN 1255 ELSE 1260
1255 DA$=DATE$:TM$=TIME$:GOTO 1400
1260 IF ASC(A$)<>73 THEN 1240
1270 LINE(0,32)-(239,63),0,BF
1280 PRINT @201,"Enter correct date using format shown";:PRINT
15      @70,"";
1290 LINE INPUT DA$
1300 LINE(0,32)-(239,63),0,BF
1310 PRINT @201,"Enter correct time using format shown";:PRINT
      @150,"";
20 1320 LINE INPUT TM$
1330 DATE$=DA$:TIME$=TM$:GOTO 1200
1400 FOR I=1 TO 6:D$(I-1)=MID$(SI$,I,1):NEXT I
1410 FOR I=1 TO 6:D$(I+5)=MID$(PI$,I,1):NEXT I
1420 D$(12)=CHR$(SN):FOR I=1 TO 4:D$(I+12)=CHR$(SC(I-1)):NEXT
25      I
1430 D$(17)=CHR$(D1)
1440 FOR I=1 TO 6:D$(I+17)=MID$(SN$,I,1):NEXT I
1450 D$(24)=CHR$(UP)
1460 D$(25)=CHR$(AP)
30 1470 FOR I=1 TO 8:D$(I+25)=MID$(DA$,I,1):NEXT I
1480 FOR I=1 TO 8:D$(I+33)=MID$(TM$,I,1):NEXT I
1490 D$(42)=CHR$(VAL(MID$(TM$,4,2)))
1492 IF ASC(D$(42))=26 THEN D$(42)=CHR$(27)
1495 D$(43)=CHR$(VAL(LEFT$(TM$,2)))
35 1496 D$(44)=CHR$(SD)

```

```

1497  D$(45)=CHR$(TD)
1498  IF ASC(D$(45))=26 THEN D$(45)=CHR$(27)
1508  FOR I=1 TO 4:D$(45+I)=CHR$(0):NEXT I
1509  REM -----LOAD FIELD UNIT-----
5   1510  OPEN "COM:28N1D" FOR INPUT AS 1
1520  OPEN "COM:28N1D" FOR OUTPUT AS 2
1530  CLS:PRINT @41,"Verify that Monitor has fresh battery";
1540  PRINT @123,"Connect Interface Unit to Monitor";
1550  PRINT @169,"Turn On Interface Unit";
10   1560  PRINT @247,"Press Monitor Reset Switch";
1600  B$=INPUT$(1,1)
1610  IF B$<>"R" THEN 1620 ELSE 1650
1620  CLS:PRINT @91,"BAD COMMUNICATION";
1630  PRINT @175,"RESTARTING";
15   1640  FOR I=1 TO 500: NEXT I:GOTO 1530
1650  CLS:PRINT @0,"Communications Established";
1700  PRINT #2,"L";:B$=INPUT$(1,1):IF B$<>"L" THEN 1620
1710  PRINT @80,"Monitor Verifies Load Mode";
1800  PRINT #2,"C";:B$=INPUT$(1,1):IF B$<>"R" THEN 1620
20   1810  PRINT @160,"Loading Data";
1820  FOR I=0 TO 49:T$=D$(I):PRINT @176,I+1,:PRINT
      #2,T$;:E$=INPUT$(1,1)
1830  IF E$<>T$ THEN 2445
1835  NEXT I
25   1840  PRINT @240,"Data Transmission Complete";
1850  FOR I=1 TO 500:NEXT I
1860  CLS:PRINT @7,"Press key 'B' to test alarm";
1870  PRINT @89,"Press key 'U' to unlock";
1900  PRINT @161,"Press Key 'C' When Tests Are Complete";
30   1920  PRINT @260,"";:A$=INPUT$(1):IF A$="Y" THEN 1990
1922  IF A$="B" THEN PRINT#2,"B";:GOTO 1920
1924  IF A$="U" THEN PRINT#2,"U";:GOTO 1920
1930  IF A$<>"C" THEN 1920
1990  PRINT #2,"C";
35   2000  B$=INPUT$(1,1):IF B$<>"F" THEN 1620

```

```
2005 REM -----PRINT RECORD-----
2010 CLS:PRINT @46,"Monitor Loading Is Complete";
2020 PRINT @121,"Turn off and disconnect Interface Unit";
2030 PRINT @203,"Printer On?, Align Top, Press 'P'";
5 2040 PRINT @237,"";:A$=INPUT$(1)
2050 IF A$<>"P" THEN 2040
2060 PRINT @292,"Printing Record";
2100 LPRINT:LPRINT
2105 LPRINT TAB(27);"MONITOR LOAD RECORD"
10 2107 LPRINT:LPRINT
2110 LPRINT "Study I.D.#";TAB(65);SI$
2120 LPRINT:LPRINT
2130 LPRINT "Patient I.D.#";TAB(65);PI$
2140 LPRINT:LPRINT
15 2150 LPRINT STRING$(71,"-")
2160 LPRINT:LPRINT
2170 LPRINT "Delivery Schedule:";TAB(65);TI$(0)
2180 IF SN>1 THEN LPRINT:LPRINT TAB(65);TI$(1) ELSE 2210
2190 IF SN>2 THEN LPRINT:LPRINT TAB(65);TI$(2) ELSE 2210
20 2200 IF SN>3 THEN LPRINT:LPRINT TAB(65);TI$(3)
2210 LPRINT:LPRINT
2220 LPRINT "      First Dosage:";TAB(65);TI$(D1)
2230 LPRINT:LPRINT
2234 LPRINT "      Start Offset:";TAB(69);SD
25 2236 LPRINT:LPRINT
2237 LPRINT "      Doses Loaded:";TAB(68);TD
2238 LPRINT:LPRINT
2240 LPRINT STRING$(71,"-")
2250 LPRINT:LPRINT
30 2260 LPRINT "Monitor Serial #";TAB(65);SN$
2270 LPRINT:LPRINT
2280 LPRINT "      Unlock Period:";TAB(63);UP$
2290 LPRINT:LPRINT
2300 LPRINT "      Alarm Start:";TAB(64);AP$
35 2310 LPRINT:LPRINT
```

```
2320 LPRINT "Date Monitor Loaded:";TAB(63);DA$  
2330 LPRINT:LPRINT  
2340 LPRINT "Time Monitor Loaded:";TAB(63);TM$  
2350 LPRINT CHR$(12):LPRINT CHR$(12)  
5 2360 REM ----- EXIT -----  
2400 CLS:PRINT @166,"Load Another Unit? (Y or N)";  
2410 PRINT @195,"";:A$=INPUT$(1)  
2420 IF A$="Y" THEN CLEAR:GOTO 150  
2430 IF A$<>"N" THEN 2410  
10 2440 CLEAR:MENU
```

CONTROLLED DISPENSING DEVICE  
"READ-M" PROGRAM LISTING

## APPENDIX III

```
10      REM      READ-M
5   20      REM      10/13/84
      30      REM      REV 05
      100     CLS:LINE (10,2)-(228,60),1,B:LINE (12,4)-(226,58),1,B
      110     PRINT @47,"MEDICAL MICROSYSTEMS, INC."
      120     PRINT @133,"Copyright 1984"
10   130     PRINT @247,"Monitor Debriefing Routine"
      135     PRINT @275, "A4"
      140     FOR I=1 TO 1000:NEXT I
      150     CLOSE:CLEAR
      200     MAXFILES=2
15   205     DIM D$(134),SC(3),SC$(3),IN(3)
      210     OPEN "COM:28N1D" FOR INPUT AS 1
      220     OPEN "COM:28N1D" FOR OUTPUT AS 2
      230     REM -----UNLOAD-----
      300     CLS:PRINT @83,"Connect Interface Unit to Monitor";
20   310     PRINT @169,"Turn ON Interface Unit";
      320     PRINT @247,"Press Monitor Reset Switch";
      400     B$=INPUT$(1,1)
      410     IF B$<>"R" THEN 420 ELSE 450
      420     CLS:PRINT @91,"BAD COMMUNICATION";
25   430     PRINT @175,"RESTARTING";
      440     FOR I=1 TO 500:NEXT I:GOTO 150
      450     CLS:PRINT @0,"Communications Established";
      460     PRINT #2,"U";:B$=INPUT$(1,1):IF B$<>"U" THEN 420
      470     PRINT @80,"Monitor Verifies Unload Mode";
30   480     PRINT #2,"C";:PRINT @160,"Unloading Data";
      485     ON ERROR GOTO 2000
      490     FOR I=1 TO 131:R$=INPUT$(1,1)
      495     D$(I-1)=R$
```

```
496 IF I=25 OR I=26 OR I=43 OR I=46 THEN 510
500 IF ASC(R$)=30 THEN 420
510 PRINT @176,I;:PRINT #2,R$;:NEXT I
530 PRINT @240,"Data Transmission Complete"
5 540 FOR I=1 TO 500:NEXT I
560 CLS:PRINT @45,"Monitor Unloading is Complete";
570 PRINT @121,"Turn OFF and disconnect Interface Unit";
580 PRINT @203,"Printer ON?, Align Top, Press 'P'";
590 PRINT @237,"";:A$=INPUT$(1)
10 639 IF A$<>"P" THEN 630
640 PRINT @295,"Computing";
641 REM -----ASSEMBLE IDENTIFYING DATA-----
642 SI$=D$(0)+D$(1)+D$(2)+D$(3)+D$(4)+D$(5)
644 PI$=D$(6)+D$(7)+D$(8)+D$(9)+D$(10)+D$(11)
15 646 SN=ASC(D$(12))
648 SC(0)=ASC(D$(13)):SC(1)=ASC(D$(14)):SC(2)=ASC(D$(15)):
      SC(3)=ASC(D$(16))
650 DI=ASC(D$(17))
651 SD=ASC(D$(44)):DT=ASC(D$(45))
20 652 SN$=D$(18)+D$(19)+D$(20)+D$(21)+D$(22)+D$(23)
654 UP=ASC(D$(24)):AP=ASC(D$(25))
656 DA$=D$(26)+D$(27)+D$(28)+D$(29)+D$(30)+D$(31)
      +D$(32)+D$(33)
658 TM$=D$(34)+D$(35)+D$(36)+D$(37)+D$(38)+D$(39)
25  +D$(40)+D$(41)
660 CT=ASC(D$(50)):IF CT>40 THEN CT=40
661 ON SN GOTO 662,663,664,665
662 IN(0)=24:GOTO 670
663 IN(0)=SC(1)-SC(0):IN(1)=SC(0)+24-SC(1):GOTO 670
30 664 IN(0)=SC(1)-SC(0):IN(1)=SC(2)-SC(1):IN(2)=SC(0)
      +24-SC(2):GOTO 670
665 IN(0)=SC(1)-SC(0):IN(1)=SC(2)-SC(1):IN(2)=
      SC(3)-SC(2):IN(3)=SC(0)+24-SC(3)
670 IF AP=58 THEN AP$="T-2 Minutes"
35 672 IF AP=45 THEN AP$="T-15 Minutes"
```

```

674  IF AP=30 THEN AP$="T-30 Minutes"
676  IF AP=61 THEN AP$="No Alarm"
680  IF UP=58 THEN UP$="T-2 Minutes"
682  IF UP=30 THEN UP$="T-30 Minutes"
5   684  IF UP=1 THEN UP$="T-59 Minutes"
686  IF UP=61 THEN UP$="Always Unlocked"
690  FOR I=1 TO 4
692  IF SC(I-1)<10 THEN SC$(I-1)="0"+RIGHT$
      (STR$(SC(I-1)),1)+"00":GOTO 696
10   694  SC$(I-1)=RIGHT$(STR$(SC(I-1)),2)+"00"
696  NEXT I
698  D1$=SC$(D1)
699  REM -----LCD REPORT-----
700  CLS:PRINT @2,"STUDY ID#";SI$;
15   720  PRINT @21,"LOAD:";DA$;
735  PRINT " ";LEFT$(TM$,5);
740  PRINT @40,"PATIENT ID#";PI$;
760  PRINT @59,"UNLOAD:";DATE$;" ";LEFT$(TIME$,5);
770  PRINT @91,"SCH: ";
20   780  FOR I=1 TO SN:PRINT " ";SC$(I-1);:NEXT I
920  LINE (0,24)-(239,63),1,B
930  LINE (0,43)-(239,43)
940  PRINT @200,"";
1000 J=51:K=D1:TT=((SD+1)*24+SC(D1))*60
25   1010 FOR I=1 TO CT
1030 GOSUB 1720
1040 IF TB<>6 THEN 1200
1050 PRINT @200+POS(0),"M";
1060 K=K+1:GOSUB 1220:TT=T1:GOSUB 1745:GOTO 1040
30   1200 PRINT @200+POS(0)+(TB-3)*40,"*";
1210 J=J+2:K=K+1:GOSUB 1220:TT=T1:GOTO 1230
1220 IF K=SN THEN K=0:Z=POS(0):LINE(Z*6-1,24)-(Z*6-1,63):
      PRINT @200+Z,"";
1225 RETURN
35   1230 NEXT I

```

```
1240 REM -----HARD COPY REPORT-----
1300 LPRINT:LPRINT
1310 LPRINT TAB(19);"COMPLIANCE MONITOR DEBRIEFING REPORT"
1320 LPRINT:LPRINT "Study I.D.#";TAB(65);SIS
5 1330 LPRINT "Patient I.D.#";TAB(65);PI$
1340 GOSUB 1345:GOTO 1350
1345 FOR I=1 TO 71:LPRINT "-";:NEXT I:LPRINT:RETURN
1350 LPRINT "Monitor Serial #";TAB(65);SNS
1360 LPRINT "Loaded on: ";DAS;" @ ";TMS
10 1370 LPRINT "Unloaded on: ";DATES;" @ ";TIME$
1380 GOSUB 1345
1390 LPRINT "Dosage Schedule:";
1400 FOR I=1 TO SN:LPRINT " ";SC$(I-1);:NEXT I
1410 LPRINT:LPRINT "First Dosage: ";D1$
15 1415 LPRINT "Start Day Offset: ";SD
1417 LPRINT "Doses Loaded: ";DT
1420 LPRINT "Unlock Period: ";UPS
1430 LPRINT "Alarm Period: ";APS
1440 GOSUB 1345
20 1500 LPRINT:LPRINT "Compliance Profile:"
1510 LPRINT TAB(12);:FOR I=1 TO 59:LPRINT "-";:NEXT I:LPRINT
1520 LPRINT TAB(12);CHR$(124);">2Hr Early
           <2Hr Early  +-1 Hour  <2Hr Late
           >2Hr Late";CHR$(124)
25 1530 GOSUB 1345
1600 J=51:K=D1:TT=((SD+1)*24+SC(D1))*60
1602 FOR I=1 TO CT
1604 GOSUB 1720
1606 IF TB<>6 THEN 1610
30 1608 GOSUB 1630:GOSUB 1800:K=K+1:GOSUB 1820:TT=T1:
           GOSUB 1745: GOTO 1606
1610 GOSUB 1630:GOSUB 1800:GOTO 1810
1620 REM -----TIME LABEL-----
1630 TA$=SC$(K)
35 1635 IF TB=6 THEN TI$="MISSED":TB=3:RETURN
```

1640 IF AH<10 THEN H\$="0"+RIGHT\$(STR\$(AH),1):GOTO 1660  
1650 H\$=RIGHT\$(STR\$(AH),2)  
1660 IF AM<10 THEN M\$="0"+RIGHT\$(STR\$(AM),1):GOTO 1680  
1670 M\$=RIGHT\$(STR\$(AM),2)  
5 1680 TI\$=H\$+M\$  
1685 DY=AD-INT(TT/1440)  
1690 IF DY=0 THEN 1715  
1700 IF DY<0 THEN TI\$=TI\$+" -"+MID\$(STR\$(ABS(DY)),2):GOTO 1715  
1710 TI\$=TI\$+" +" +MID\$(STR\$(ABS(DY)),2)  
10 1715 RETURN  
1717 REM -----UNPACK DATA & ERROR CALC-----  
1720 B1=ASC(D\$(J)):IF B1=31 THEN B1=26  
1721 B2=ASC(D\$(J+1)):IF B2=31 THEN B2=26  
1722 B3=B1:GOSUB 1726:AH=B3  
15 1724 B3=B2:GOSUB 1726:AM=B3\*2:GOTO 1734  
1726 IF B3>127 THEN B3=B3-128  
1728 IF B3>63 THEN B3=B3-64  
1730 IF B3>31 THEN B3=B3-32  
1732 RETURN  
20 1734 AD=0:B3=B2  
1736 IF B3>127 THEN AD=AD+32:B3=B3-128  
1737 IF B3>63 THEN AD=AD+16:B3=B3-64  
1738 IF B3>31 THEN AD=AD+8  
1739 B3=B1  
25 1740 IF B3>127 THEN AD=AD+4:B3=B3-128  
1742 IF B3>63 THEN AD=AD+2:B3=B3-64  
1744 IF B3>31 THEN AD=AD+1  
1745 T1=TT+IN(K)\*60:R2=((AD\*24+AH)\*60+AM)-T1  
1746 IF R2>-61 THEN TB=6:RETURN  
30 1747 ER=((AD\*24+AH)\*60+AM)-TT  
1750 IF ER>120 THEN TB=5:GOTO 1790  
1760 IF ER>60 THEN TB=4:GOTO 1790  
1770 IF ER>-61 THEN TB=3:GOTO 1790  
1780 IF ER>-121 THEN TB=2:GOTO 1790  
35 1785 TB=1

```
1790 RETURN
1795 REM -----PRINT LOCATION-----
1800 LPRINT CHR$(124);RIGHT$(STR$(I),2);CHR$(124);";";TA$;;
      ";CHR$(124);TAB(3+TB*12);TI$;TAB(70);CHR$(124)
5 1805 RETURN
1810 J=J+2:K=K+1:GOSUB 1820:TT=T1:GOTO 1825
1820 IF K=SN THEN K=0:Z1=I:GOSUB 1345:I=Z1
1822 RETURN
1825 NEXT I
10 1826 REM -----EXIT-----
1830 GOSUB 1345:LPRINT CHR$(12):LPRINT CHR$(12)
1900 CLS:PRINT @165,"Unload Another Unit? (Y or N)";
1910 PRINT @195,"";:A$=INPUT$(1)
1920 IF A$="Y" THEN CLEAR:GOTO 150
15 1930 IF A$<>"N" THEN 1910
1940 CLEAR:MENU
2000 IF ERR = 54- THEN 2020
2005 IF ERR=5 THEN 1240
2010 PRINT ERR:PRINT ERL:STOP
20 2020 CLOSE 1: OPEN "COM:28NID" FOR INPUT AS 1
2025 PRINT "EOF"
2030 RESUME NEXT
```

WHAT IS CLAIMED IS:

1. A dispensing device, comprising:  
a storage compartment;  
a sleeved strip having a plurality of  
5 containers mounted thereon for maintaining a  
predetermined order of said containers, said  
sleeved strip and containings being stored within  
said storage compartment;  
dispensing means for dispensing, upon  
10 each actuation thereof, one container, said  
dispensing means including an ejector element  
mounted for rotation about a longitudinal axis  
thereof and having container conforming  
depressions around its periphery, said depressions  
15 being shaped so as to engage and convey individual  
containers arranged in said storage compartment in  
their order along said sleeved strip; said ejector  
element; when rotated through a predetermined  
angle, causing one container to be dispensed and  
20 the next container in sequence along said sleeve  
to be moved into a position ready to be dispensed  
upon the next ejector rotation; and means for  
actuating said dispensing means.
2. A device according to claim 1 wherein  
25 said storage compartment includes a partition  
defining a passageway in which said sleeve and  
containers are stored.
3. A device according to claim 2 wherein  
said passageway has a width that is less than two  
30 container diameters.

4. A device according to claim 1 wherein  
said ejector element has substantially a cross-  
sectional form of a square with semicircular  
depressions in each side of the square for  
5 engaging cylindrical-shaped containers.

5. A device according to claim 1 wherein  
said dispensing means further includes means for  
preventing rotation of the ejector element in a  
direction opposite to that of rotation to dispense  
10 a container.

6. A device according to claim 1 wherein  
said dispensing means further includes a stop  
arrangement, operable in set and reset positions,  
that prevents after each container is dispensed,  
15 further dispensing action until the stop mechanism  
is reset.

7. A device according to claim 6 further  
including means for resetting said stop mechanism  
by means of linkages accessible to a user.

20 8. A device according to claim 6 wherein  
the stop mechanism includes latching means for  
preventing movement of the stop mechanism out of  
its set or reset positions.

9. A device according to claim 1 wherein  
25 said sleeved strip is adapted so that after it is  
loaded with containers, it can be folded into said  
storage compartment back and forth across a  
passageway thereof such that containers earlier in  
said predetermined order are nearer the dispensing  
30 means than containers later in the order.

10. A dispensing device, comprising:  
a storage compartment for storing a  
plurality of containers to be dispensed one at a  
time in predetermined order;  
5 means, upon an actuation thereof, for  
dispensing a container from said storage  
compartment;  
means for storing a dispensing schedule  
specifying when a dispensing operation can be  
10 carried out by said dispensing means;  
means for alerting a user as to scheduled  
dispensing times;  
means for modifying a schedule stored in  
said storing means in response to dispensing  
15 operations of said dispensing means; and  
means for inhibiting operation of said  
dispensing means other than at time specified by  
said schedule, as modified.

20 11. A dispensing device according to  
claim 10 wherein said alerting means comprises an  
audible alarm.

12. A dispensing device according to  
claim 10 wherein said alerting means comprises a  
25 visual indicator.

13. A dispensing device, comprising:  
storage means for storing a plurality of  
individual containers;  
dispensing means for dispensing one  
30 container at a time from said storage means, each  
container being dispensed by executing an  
individual dispensing operation;

sequencing means for maintaining a predetermined order among the individual containers so that the individual containers are dispensed in said predetermined order by said dispensing means, said sequencing means also including means for providing a predetermined spacing relationship between containers so that they can be engaged by the dispensing means;

5 electronic memory means for storing data including instructions for operating the device;

10 electronic time keeping means for providing time information;

electronic logic means for interpreting and executing said instructions;

15 means for supplying electrical power to the time keeping means, logic means and memory means; and

a housing containing said storage means, dispensing means, sequencing means, memory means,

20 time keeping means, logic means, and power supplying means.

14. A device according to claim 13 further including means for sensing and signalling for said logic means, each completed dispensing 25 operation of said dispensing means.

15. A device according to claim 13 wherein said storage means includes a substantially 'U' shaped partition defining a passageway.

30 16. A device according to claim 13 wherein said storage means includes a passageway having a width less than two container diameters.

17. A device according to claim 13 wherein said dispensing means comprises: an ejector element mounted for rotation about a longitudinal axis thereof and having container conforming depressions around its periphery, said depressions being shaped so as to engage and convey individual containers arranged in said storage means in said predetermined order; said ejector element, when rotated through a predetermined angle, causing one container to be dispensed and the next container in sequence to be moved into a position ready to be dispensed upon the next ejector rotation.

18. A device according to claim 17 wherein said ejector element has substantially a cross-sectional form of a square with semicircular depressions in each side of the square for engaging cylindrical-shaped containers.

19. A device according to claim 17 wherein said dispensing means further includes reverse rotation preventing means for preventing potentially harmful rotation of the ejector element in the direction opposite that used to dispense a container.

20. A device according to claim 19 wherein operation of said reverse rotation preventing means, through a common mechanism, simultaneously produces a completed dispensing operation signal.

21. A device according to claim 13 wherein said dispensing means includes a stop arrangement, operable in set and reset positions, that prevents, after each container is dispensed, 5 further dispensing action until the stop mechanism is reset.

22. A device according to claim 21 further including means for resetting said stop mechanism by means of linkages accessible to a 10 user.

23. A device according to claim 21 further including a solenoid and linkages for resetting said stop mechanism under control of said electronic logic means in accordance with 15 said stored instructions thereby controlling the operator's ability to dispense containers, according to said instructions.

24. A device according to claim 23 further comprising a power source separate from 20 said power supplying means for powering the solenoid.

25. A device according to claim 21 wherein the stop mechanism includes latching means for preventing movement of the stop mechanism out 25 of its set or reset positions except as provided for by said instructions.

26. A device according to claim 13 further comprising audible indicating means, controlled by said logic means, for alerting a 30 user as to when a container should be dispensed

according to a predetermined schedule defined by said instructions.

27. A device according to claim 26 wherein said audible indicating means comprises a 5 piezoelectric alarm.

28. A device according to claim 13 further comprising visual indicating means, controlled by said logic means, for prompting a user as to when a container should be dispensed 10 according to a predetermined schedule defined by said instructions.

29. A device according to claim 28 wherein said visual indicating means comprises a liquid crystal display.

15 30. A device according to claim 13 wherein said sequencing means comprises a thin, flexible strip with regularly spaced sleeves for holding individual containers, one in each sleeve, in a predetermined order.

20 31. A device according to claim 30 wherein said thin, flexible strip is adapted so that after it is loaded with containers, it can be folded into said storage means back and forth across a passageway thereof such that the 25 containers may be dispensed by the dispensing means in said predetermined order.

32. A device according to claim 14 further comprising second memory means for storing

data, including times of actual dispensing of containers.

33. A device according to claim 32 further comprising communication means for 5 transmitting said data from the device.

34. A device according to claim 13 further comprising communicating means for receiving all or part of said instructions and storing them in said memory means.

10 35. A device according to claim 14 wherein said sensing and signalling means comprises electrical switches activated by actuators following cams of the dispensing means.

15 36. A device according to claim 13 wherein the means for supplying electrical power comprises a battery.

20 37. A device according to claim 13 wherein said storage means is in a portion of said housing that is separable from the remainder of the device to facilitate the use of alternative 25 storage means in an interchangeable manner.

25 38. A device according to claim 13 wherein the means for supplying electrical power comprises a connector for coupling to an external power source.

39. A device according to claim 13 wherein the housing includes a cabinet lock and tamper-resistant fasteners for preventing

unauthorized access to the containers and mechanisms interior of said housing.

40. A device according to claim 13 wherein said dispensing means is driven manually.

5 41. A device according to claim 13 wherein said dispensing means is driven primarily by means of power not supplied by a user.

42. A dispensing system comprising:  
one or more field units, each field unit  
10 including

storage means for storing a plurality of individual containers;

dispensing means for dispensing one container at a time from said storage means, each  
15 container being dispensed by executing an individual dispensing operation;

20 sequencing means for maintaining a predetermined order among the individual containers so that the individual containers are dispensed in said predetermined order by said dispensing means, said sequencing means also including means for providing a predetermined spacing relationship between containers so that they can be engaged by the dispensing means;

25 electronic memory means for storing data, including instructions for operating the device;

electronic time keeping means for providing time information;

30 electronic logic means for interpreting and executing said instructions;

means for communicating data to/from said field unit;

means for supplying electrical power to the time keeping means, logic means, memory and 5 communicating means; and

a housing containing said storage means, dispensing means, sequencing means, memory means, time keeping means, logic means, communicating means and power supplying means; and

10 a base unit for transferring said data to/from said field unit and/or preparing a report of said data sent or received.

43. A system according to claim 42 wherein said field unit further includes means for 15 sensing and signalling to said logic means, each completed dispensing operation of said dispensing means.

44. A system according to claim 42 wherein said storage means includes a 20 substantially 'U' shaped partition defining a passageway.

45. A system according to claim 42 wherein said storage means includes a passageway having a width less than two container diameters.

25 46. A system according to claim 42 wherein said dispensing means comprises: an ejector element mounted for rotation about a longitudinal axis thereof and having container conforming depressions around its periphery, said 30 depressions being shaped so as to engage and convey individual containers arranged in said

storage means in said predetermined order; said ejector element, when rotated through a predetermined angle, causing one container to be dispensed and the next container in sequence to be 5 moved into a position ready to be dispensed upon the next ejector rotation.

47. A system according to claim 46 wherein said ejector element has substantially a cross-sectional form of a square with semicircular 10 depressions in each side of the square for engaging cylindrical-shaped containers.

48. A system according to claim 46 wherein said dispensing means further includes reverse rotation preventing means for preventing 15 potentially harmful rotation of the ejector element in the direction opposite that used to dispense a container.

49. A system according to claim 48 wherein operation of said reverse rotation 20 preventing means, through a common mechanism simultaneously produces a completed dispensing operation signal.

50. A system according to claim 42 wherein said dispensing means includes a stop 25 arrangement, operable in set and reset positions, that prevents, after each container is dispensed, further dispensing action until the stop mechanism is reset.

51. A system according to claim 50 further including means for resetting said stop mechanism by means of linkages accessible to a user.

5 52. A system according to claim 50 further including a solenoid and linkages for resetting said stop mechanism under control of said electronic logic means in accordance with said stored instructions thereby controlling the 10 operator's ability to dispense containers, according to said instructions.

53. A system according to claim 52 wherein a power source separate from said power supplying means is used for powering the solenoid.

15 54. A system according to claim 50 wherein the stop mechanism includes latching means for preventing movement of the stop mechanism out of its set or reset positions except as provided by said instructions.

20 55. A system according to claim 42 further comprising audible indicating means, controlled by said logic means, for alerting a user as to when a container should be dispensed according to a predetermined schedule defined by 25 said instructions.

56. A system according to claim 55 wherein said audible indicating means comprises a piezoelectric alarm.

57. A system according to claim 42 further comprising visual indicating means, controlled by said logic means, for prompting a user as to when a container should be dispensed 5 according to a predetermined schedule defined by said instructions.

58. A system according to claim 57 wherein said visual indicating means comprises a liquid crystal display.

10 59. A system according to claim 42 wherein said sequencing means comprises a thin, flexible strip with regularly spaced sleeves for holding individual containers, one in each sleeve, in a predetermined order.

15 60. A system according to claim 59 wherein said thin, flexible strip is adapted so that after it is loaded with containers, it can be folded into said storage means back and forth across a passageway thereof so that the containers 20 may be dispensed by the dispensing means in said predetermined order.

25 61. A system according to claim 43 further comprising second memory means for storing data including times of actual dispensing of containers.

62. A system according to claim 61 wherein said communicating means transmits said data from the device to said base unit.

63. A system according to claim 62  
wherein said base unit comprises a general purpose  
computer, specially programmed to carry out its  
functions of debriefing said field unit of said  
5 data including times of actual dispensing and  
preparing a report of actual dispensing data.

64. A system according to claim 42  
wherein said communicating means receives from the  
base unit all or part of said instructions for  
10 storage in said memory means,

65. A system according to claim 64  
wherein said base unit comprises a general purpose  
computer, programmed to carry out its functions of  
transmitting all or part of said instructions to  
15 said field unit before the field unit is used for  
dispensing.

66. A system according to claim 43  
wherein said sensing and signalling means  
comprises electrical switches activated by  
20 actuators following cams of the dispensing means.

67. A system according to claim 42  
wherein the means for supplying electrical power  
comprises a battery.

68. A system according to claim 42  
25 wherein the means for supplying electrical power  
comprises a connector for coupling to an external  
power source.

69. A system according to claim 42 wherein said housing includes a cabinet lock and tamper-resistant fasteners for preventing unauthorized access to said containers and 5 mechanisms interior of said housing.

70. A device according to claim 42 wherein said dispensing means is driven manually.

71. A device according to claim 42 wherein said dispensing means is driven primarily 10 by power not supplied by a user.

72. A system according to claim 42 wherein the storage means is in a portion of the housing that is separable from the remainder of the device, such that alternative storage means, 15 each holding containers of different capacity, may be used interchangeably.

73. A medication dispensing device, comprising:

medication storage means for storing a 20 plurality of individual medication containers arranged in a predetermined sequence; means for storing a drug therapy schedule defining predetermined times and conditions under which medication containers should be dispensed 25 from said medication storage means;

dispensing means for dispensing from said medication storage means, in response to a patient manipulation thereof at one of said predetermined times of said drug therapy schedule, a medication 30 container;

means for storing information as to the times of actual dispensing of containers for reporting patient compliance with the drug therapy schedule.

5        74. A device according to claim 73 further including indicator means for indicating to a patient when he should dispense a medication container and administer to himself a medication contained therein.

10       75. A device according to claim 73 wherein said dispensing means further includes means for preventing the dispensing of a container at times other than said predetermined times of said drug therapy schedule.

15       76. A device according to claim 74 wherein said indicating means comprises audible alarm means for alerting the patient when one of said predetermined times is near or has passed without a dispensing of a medication container.

20       77. A device according to claim 76 wherein said audible alarm means comprises a piezoelectric alarm.

25       78. A device according to claim 73 wherein said therapy schedule further includes instructions for changing the drug therapy schedule in response to a failure of the patient to dispense a medication container at one or more of said predetermined times.

79. A device according to claim 73 further comprising means for transmitting information stored in said storing means.

80. A device according to claim 73  
5 further comprising means for communicating the drug therapy schedule to said drug schedule storage means.

81. A device according to claim 73  
wherein said medication containers are vials  
10 attached to a belt.

82. A device according to claim 74  
wherein said indicator means comprises a digital display for indicating when a next dosage is due to be dispensed according to said schedule.

15 83. A device according to claim 75  
wherein said dispensing means comprises a locking arrangement for blocking free access to said containers; a solenoid for unlocking said locking arrangement so that the dispensing means can be  
20 manually manipulated at said predetermined times; and microprocessor means for controlling said solenoid according to said schedule.

84. A device according to claim 73  
wherein said dispensing means comprises a sprocket  
25 mounted for rotation about a longitudinal axis thereof and having grooves therein for accommodating and conveying said containers.

85. A device according to claim 84  
further comprising electrical switches coupled so

as to be actuated by rotation of said sprocket,  
said switches providing said information as to the  
times of actual dispensing of containers.

86. A medication dispensing system,  
5 comprising:

a base unit for defining a drug  
dispensing schedule according to which a field  
unit is to dispense drugs, debriefing the field  
unit after it has dispensed drugs, and providing a  
10 report on the information debriefed; and  
a field unit including means for  
receiving drugs to be dispensed, means for  
receiving and storing the dispensing schedule from  
said base unit, means for permitting drugs to be  
15 dispensed according to said schedule, means for  
recording actual times of drug dispensing, and  
means for transmitting the recorded information to  
said base unit.

87. A system according to claim 86  
20 further comprising additional field units, each of  
which can be operated with said base unit.

88. A system according to claim 86  
wherein said base unit comprises a computer  
programmed to carry out its defining, debriefing  
25 and reporting functions.

89. A system according to claim 88  
wherein said field unit comprises:  
medication storage means for storing a  
plurality of individual medication containers  
30 arranged in a predetermined sequence;

means for storing said dispensing schedule;

5 indicator means for indicating to a user when he should dispense a medication container and administer to himself a medication contained therein; and

10 dispensing means for dispensing from said medication storage means, in response to a patient manipulation thereof at one of said predetermined times of said schedule, a medication container.

15 90. A system according to claim 89 wherein said dispensing means further comprises means for preventing the dispensing of a container at times other than said predetermined times of said schedule.

20 91. A system according to claim 89 wherein said field unit further comprises means for storing information as to the times of actual dispensing of containers for reporting compliance with said schedule.

25 92. A system according to claim 89 wherein said indicator means includes audible alarm means for alerting the user when a dispensing time is near or has passed without a dispensing of a medication container.

93. A system according to claim 92 wherein said alarm means comprises a piezoelectric alarm.

30 94. A system according to claim 89 wherein said field unit further includes means for

changing the dispensing schedule in response to a failure of the patient to dispense a medication container at a dispensing time.

95. A system according to claim 89  
5 wherein said medication containers are vials  
attached to a belt.

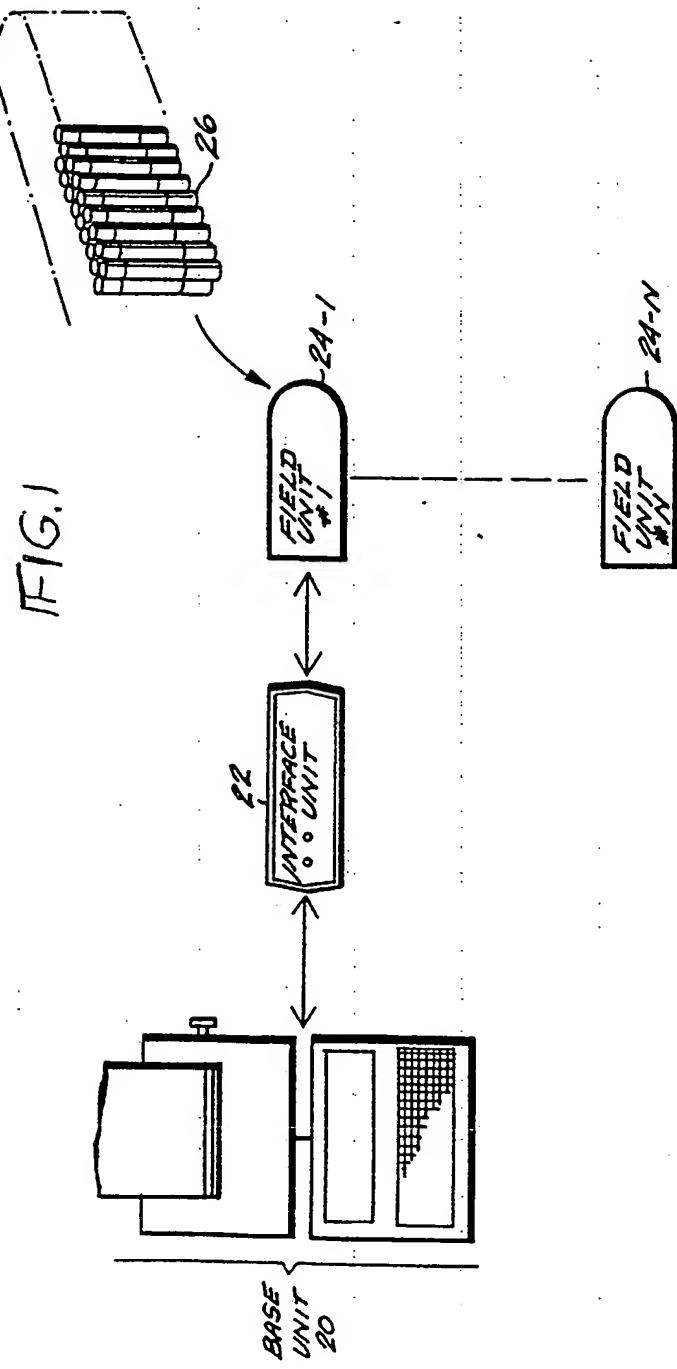
96. A system according to claim 89  
wherein said indicator means comprises a digital  
display for indicating when a next dosage is due  
10 to be dispensed according to said schedule.

97. A system according to claim 90  
wherein said dispensing means comprises a locking  
arrangement for blocking free access to said  
containers; a solenoid for unlocking said locking  
15 arrangement so that the dispensing means can be  
manually manipulated at said predetermined times;  
and microprocessor means for controlling said  
solenoid according to said schedule.

98. A system according to claim 89  
20 wherein said dispensing means comprises a sprocket  
mounted for rotation about a longitudinal axis  
thereof and having grooves therein for  
accommodating and conveying said containers.

99. A system according to claim 98  
25 further comprising electrical switches coupled so  
as to be actuated by rotation of said sprocket,  
said switches providing said information as to the  
times of actual dispensing of containers.

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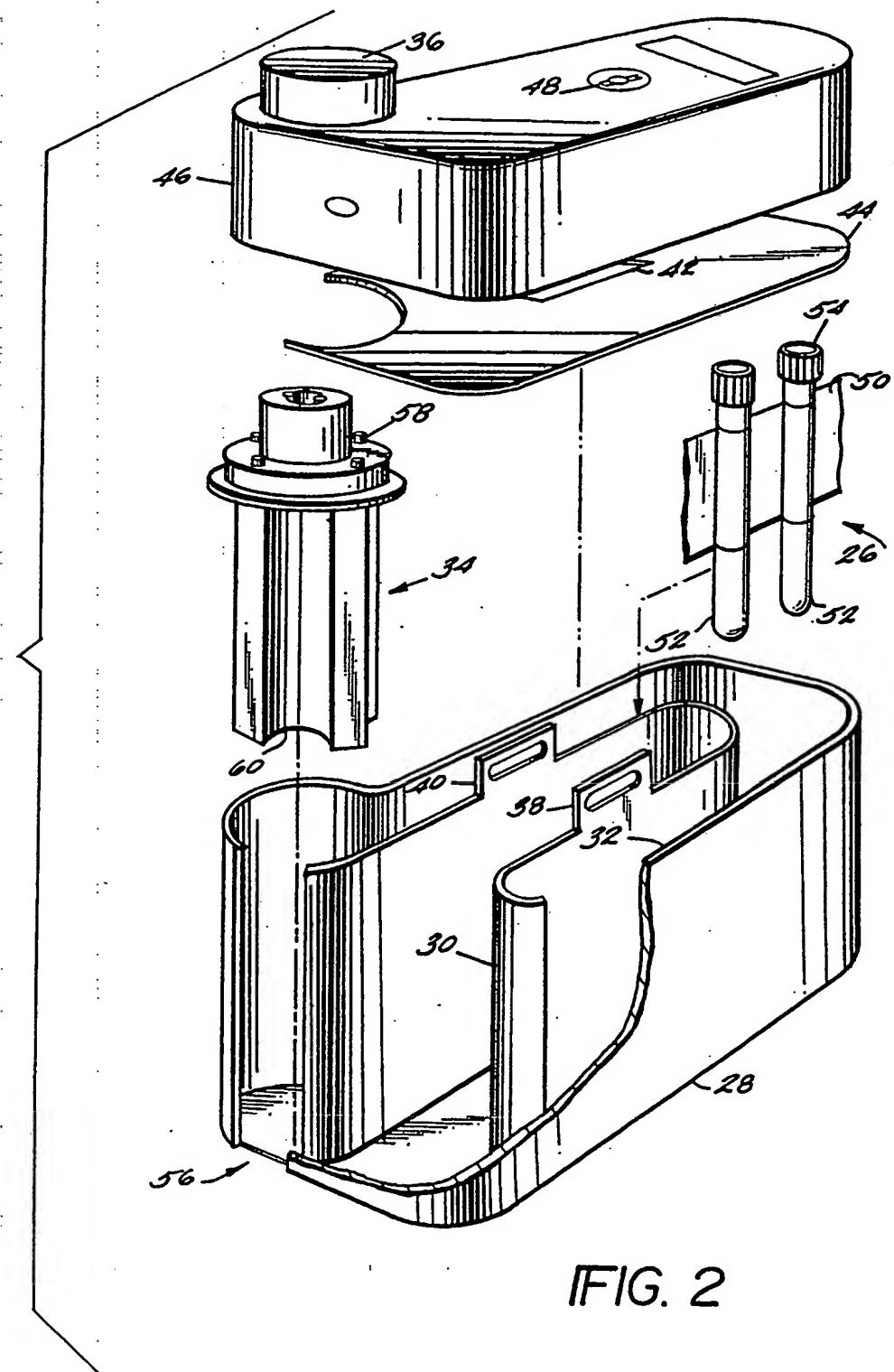


FIG. 2

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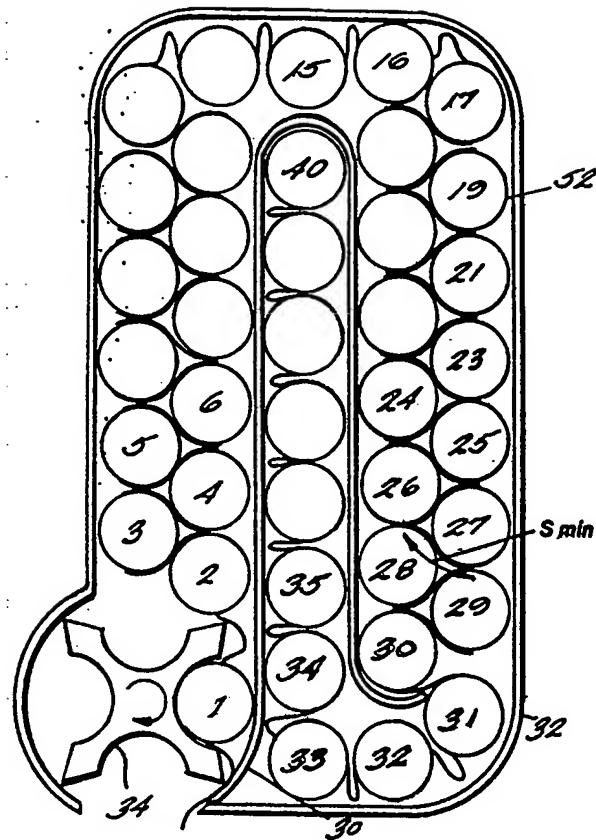


FIG. 4

FIG. 3

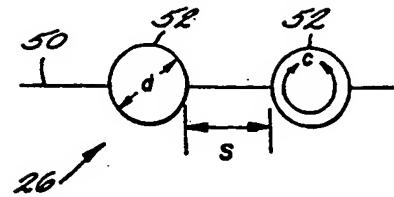


FIG. 5

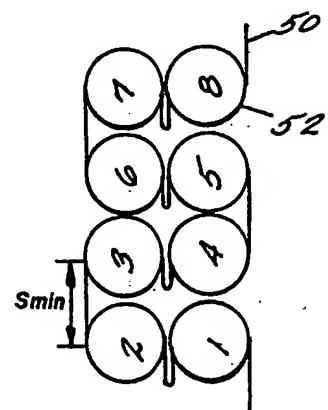


FIG. 6

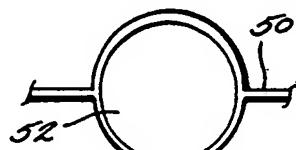


FIG. 7

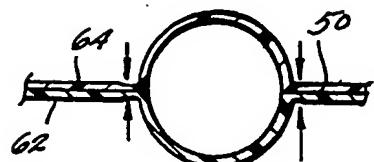


FIG. 9

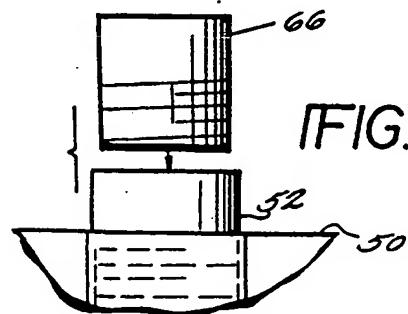
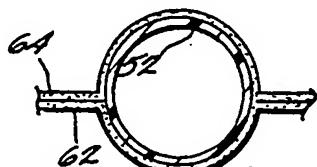


FIG. 8



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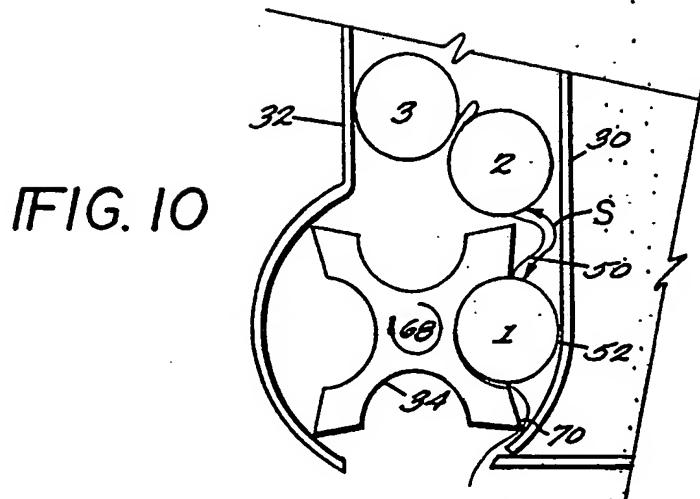
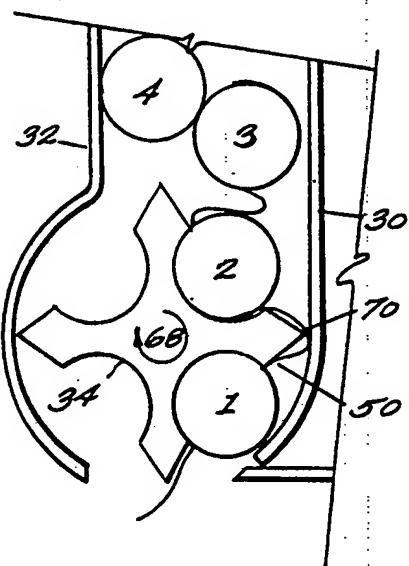


FIG. 10



## FIG. II

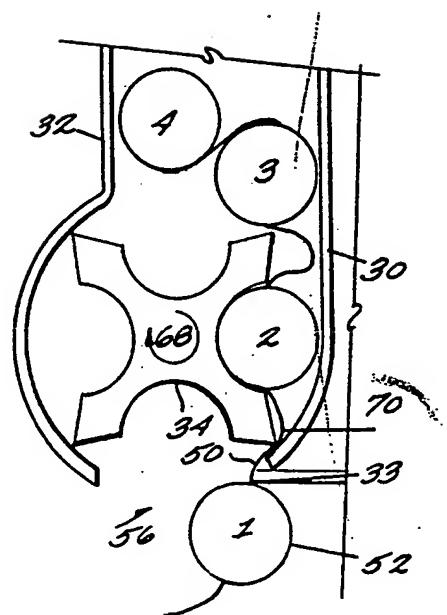


FIG. 12

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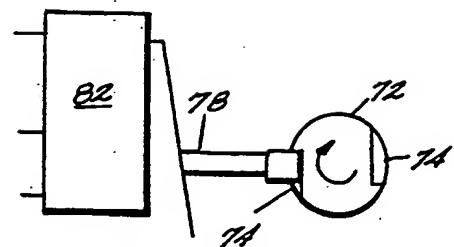


FIG. 15

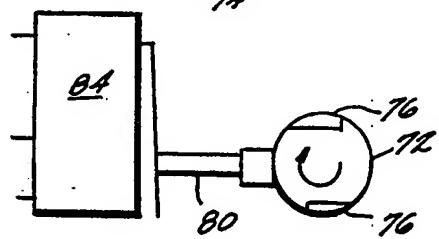


FIG. 16

FIG. 13

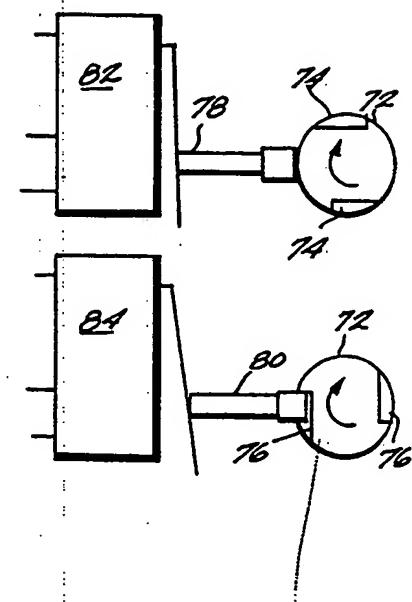
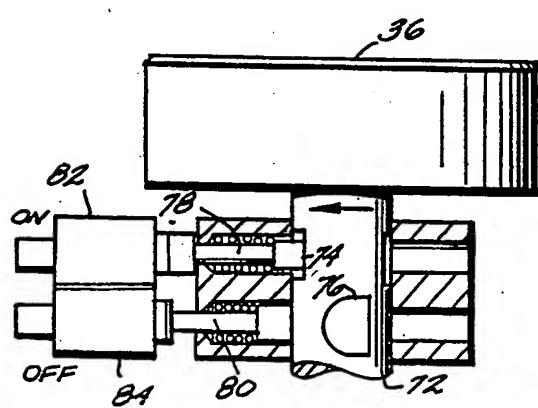
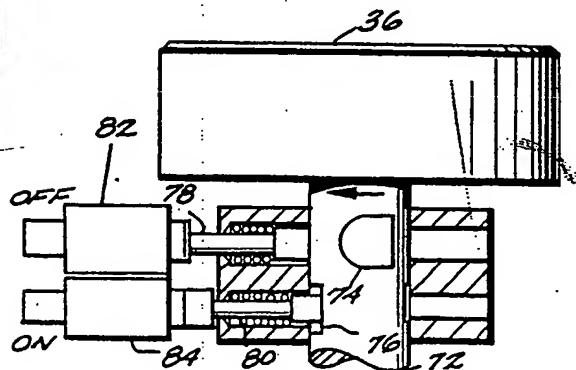


FIG. 14



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FIG. 17

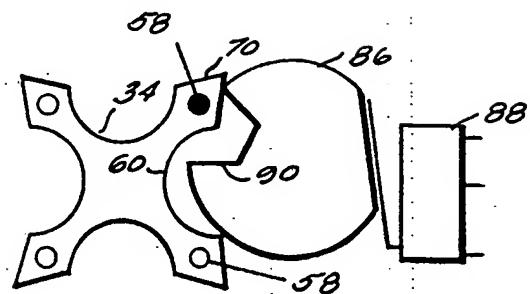


FIG. 18

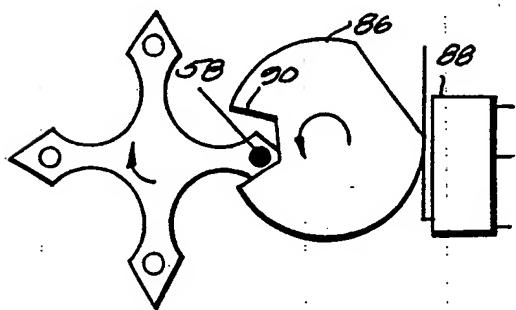


FIG. 19

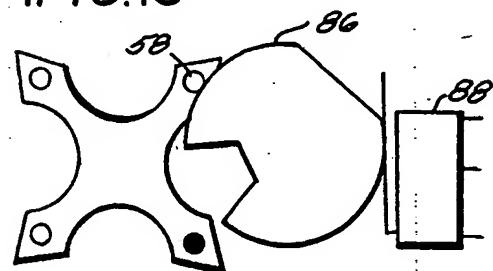


FIG. 21

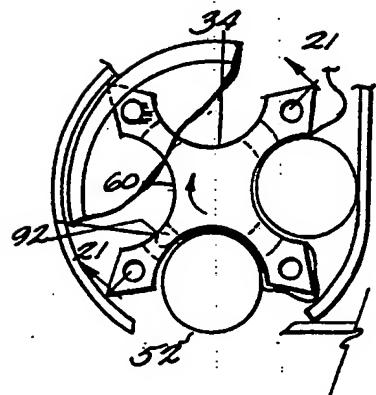


FIG. 22

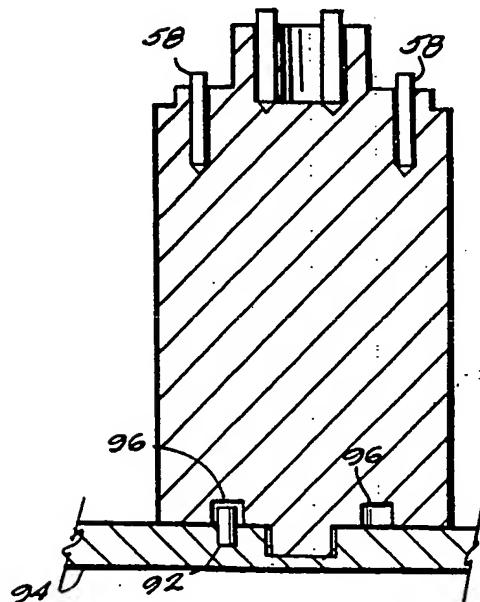
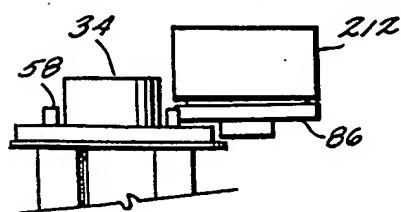


FIG. 20



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FIG.24

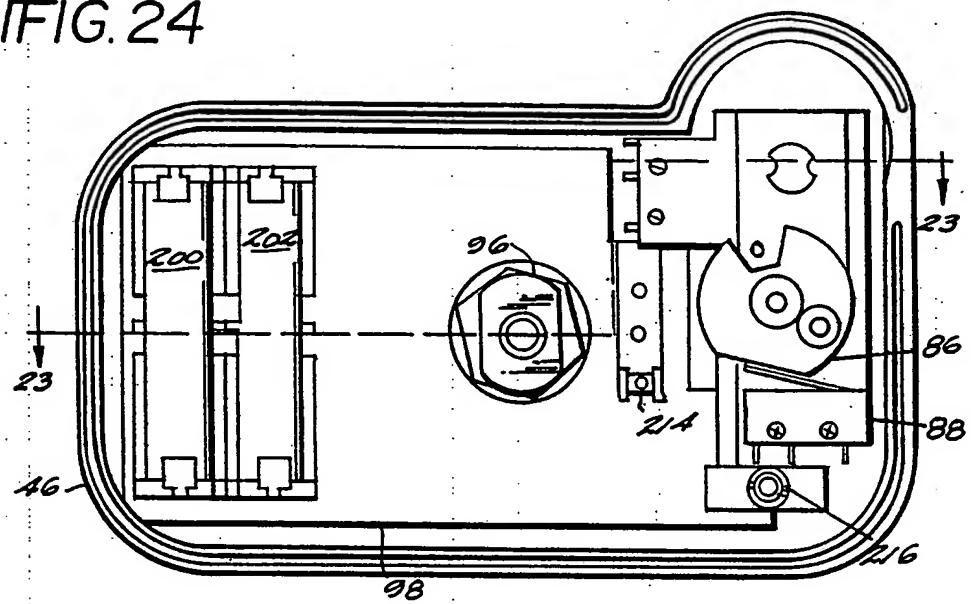
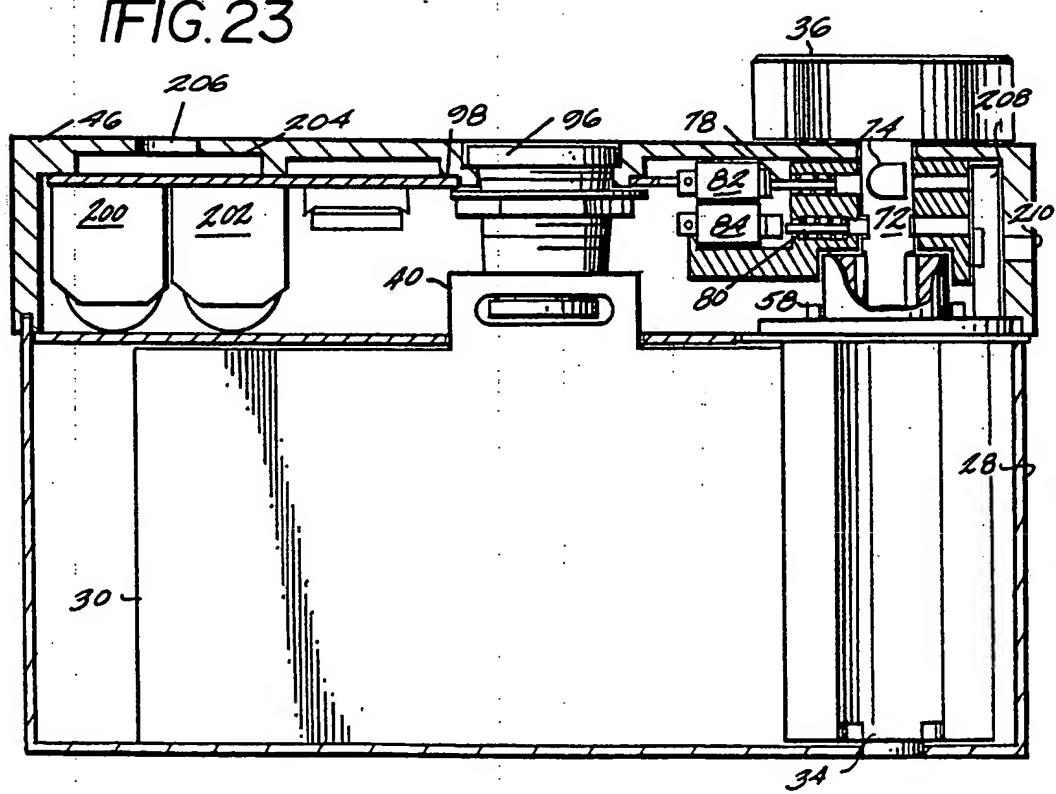
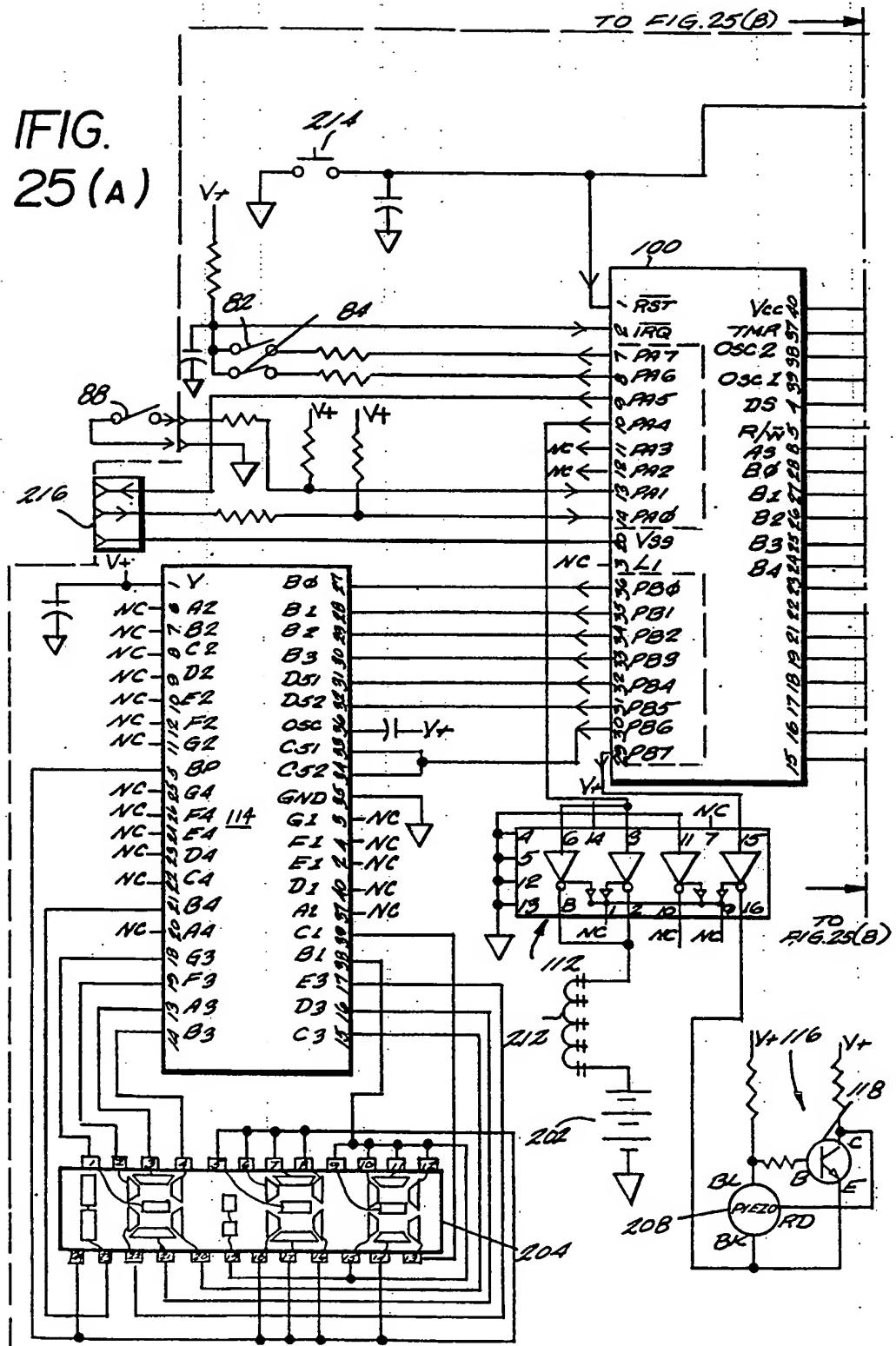


FIG.23



— CHFFET

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FIG.  
25 (A)

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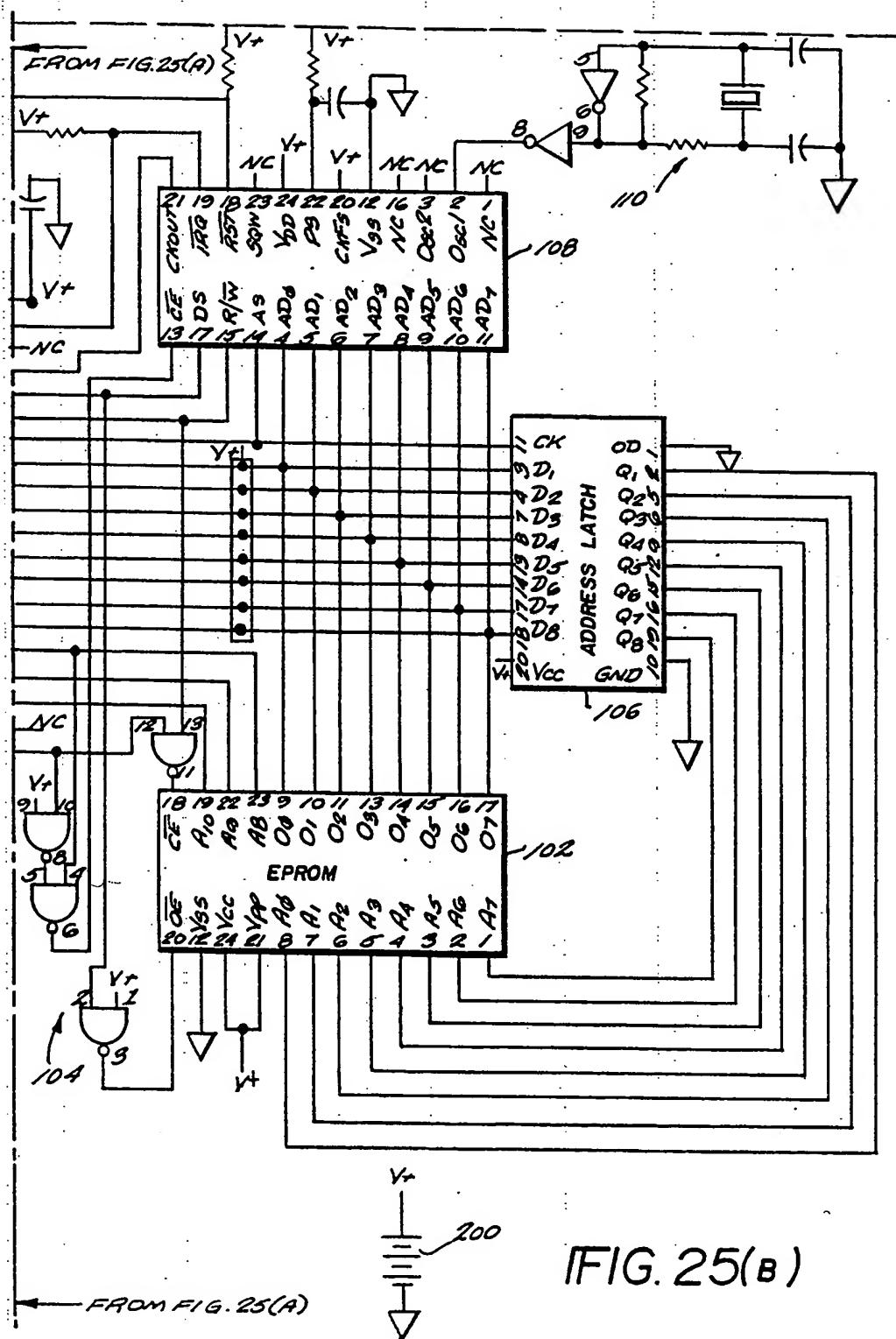
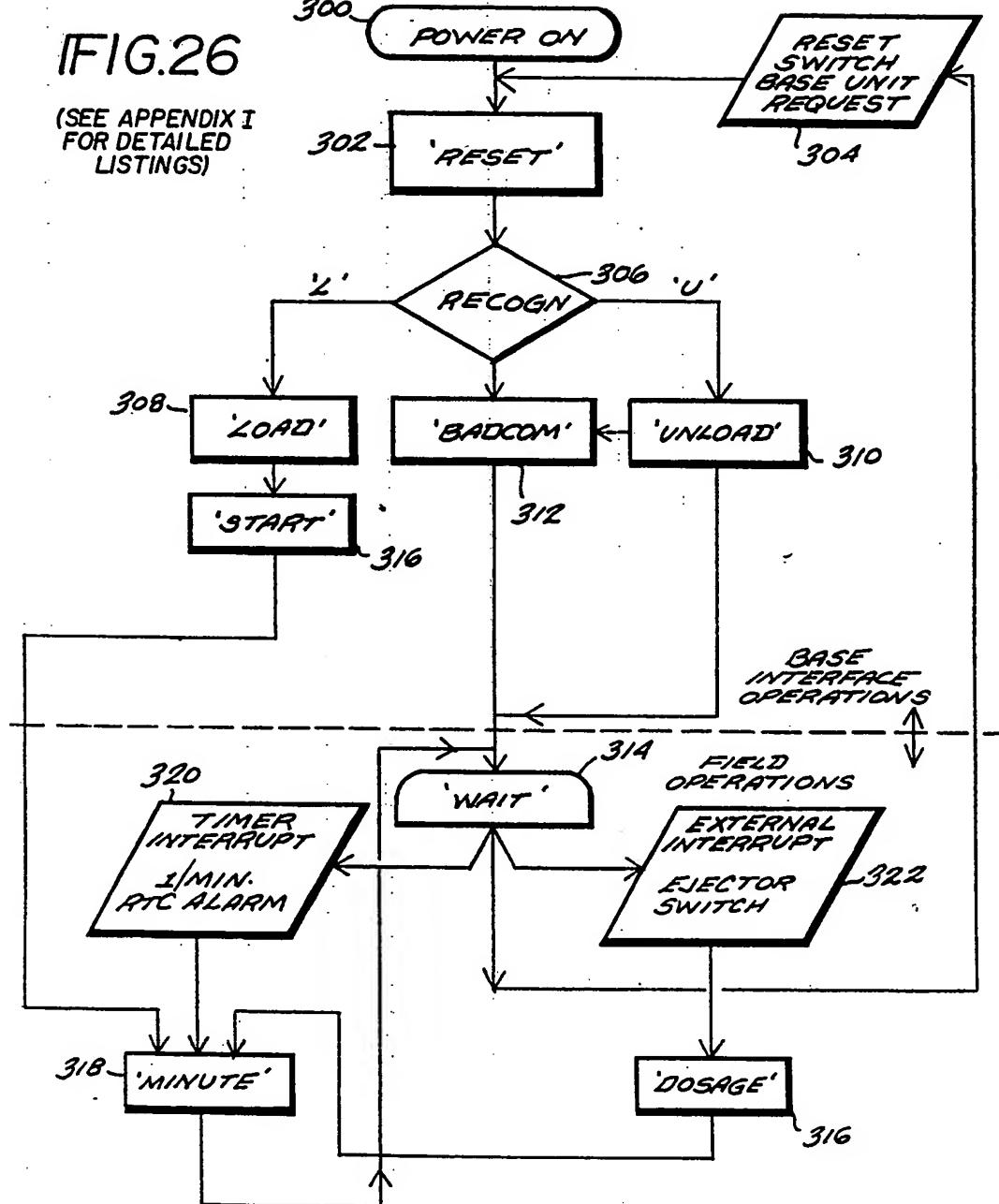


FIG. 25(B)

----- OUTPUT -----

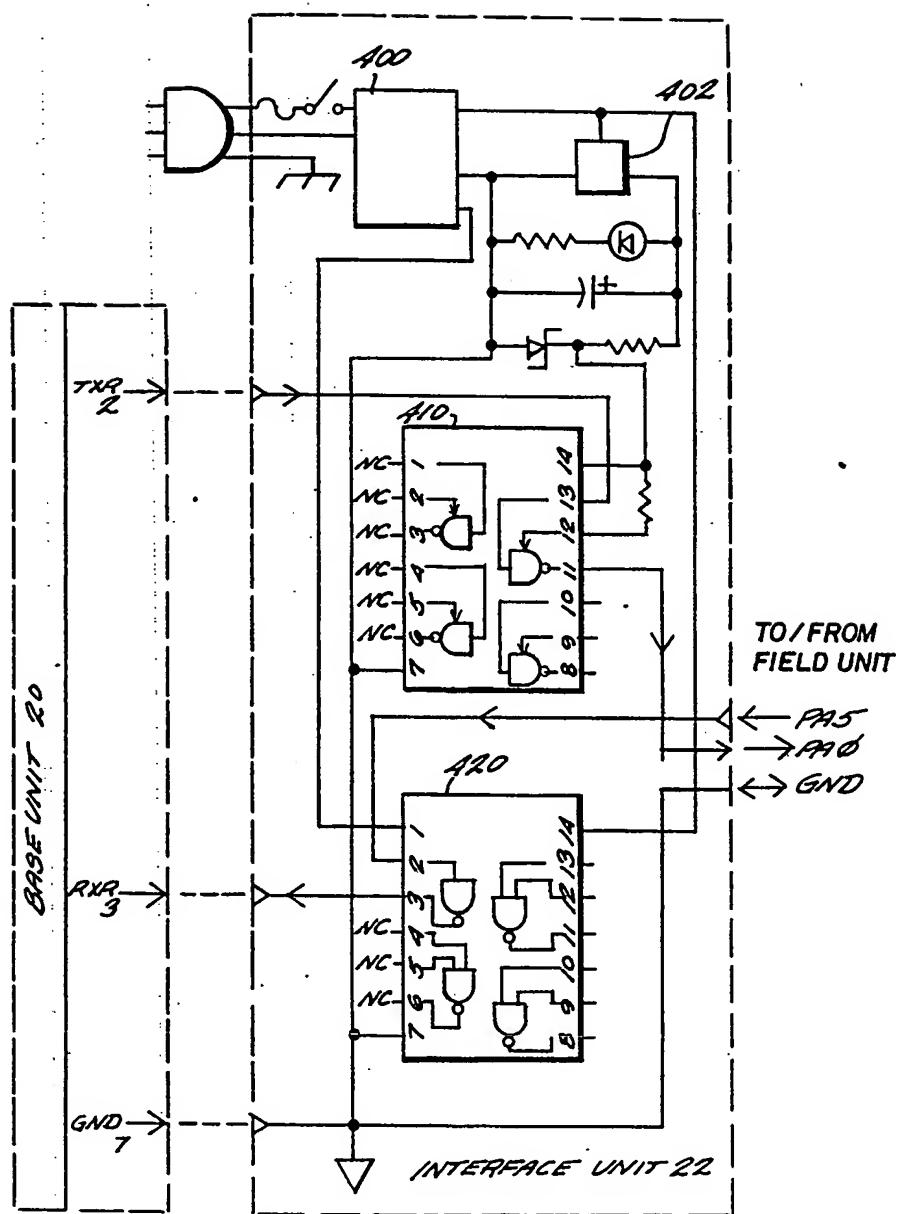
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FIG.26

(SEE APPENDIX I  
FOR DETAILED  
LISTINGS)

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FIG. 27



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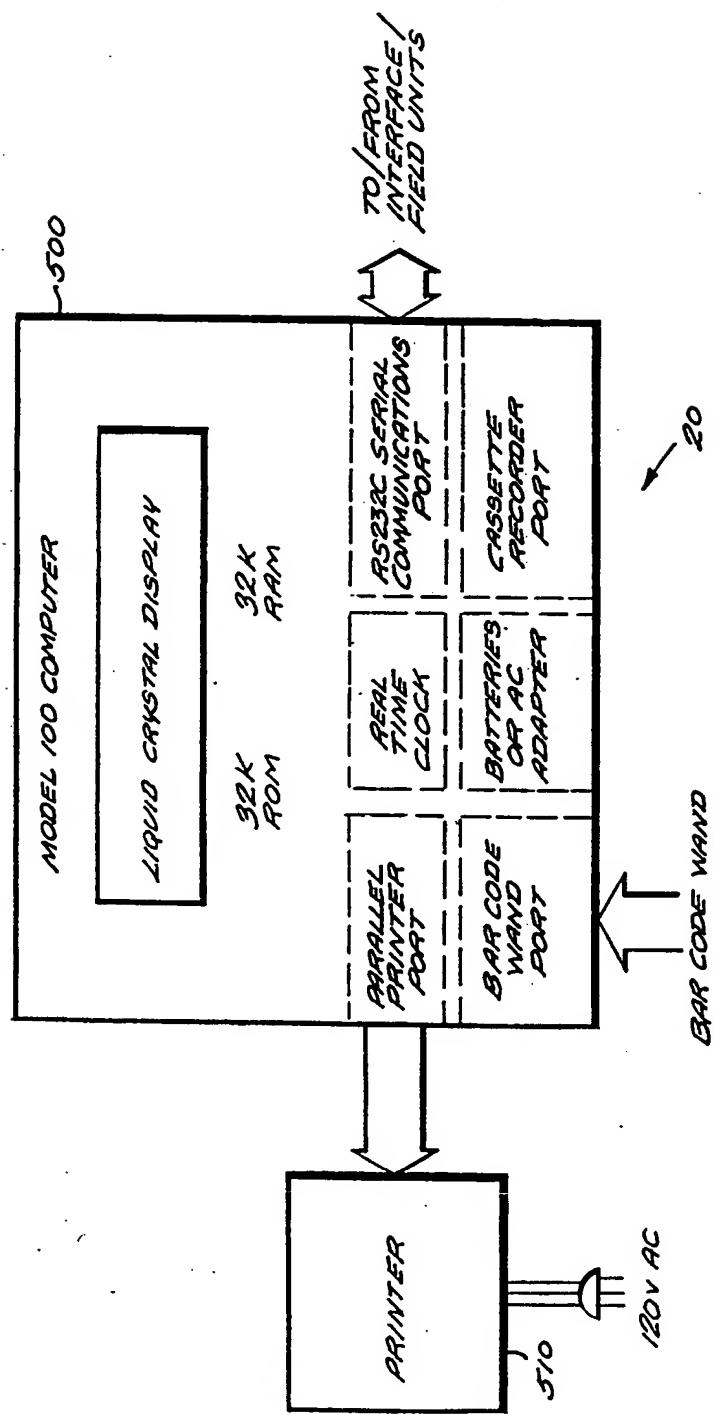


FIG. 28

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"LOAD-M" ROUTINE  
(SEE APPENDIX II  
FOR LISTING)

GATHER  
IDENTIFYING  
AND  
SCHEDULE  
DATA

LOAD/ TEST  
FIELD UNIT

PRINT FILE  
COPY

EXIT



INPUT STUDY ID #

INPUT PATIENT ID #

INPUT DAILY SCHEDULE

INPUT FIRST DOSAGE

INPUT STARTING DAY OFFSET

INPUT #DOSES LOADED

INPUT MONITOR SERIAL #

INPUT LOCK PERIOD

INPUT ALARM START

CHECK/CORRECT BASE UNIT REAL TIME CLOCK

DISASSEMBLE/ CODE INPUT INFORMATION INTO  
50 BYTES OF DATA READY FOR TRANSMISSION

RETRY

SEND 50 BYTES  
OF DATA TO INTER-  
FACE/FIELD UNITS

BAD  
ECHO

PROMPT  
'END' COM-  
MUNICATIONS

ALLOW TEST OF FIELD UNIT  
ALARM AND UNLOCK SOLENOID

PRINT HARD COPY OF  
LOADED DATA  
(SEE SAMPLE)

LOAD  
ANOTHER  
UNIT?

YES

NO



FIG. 29

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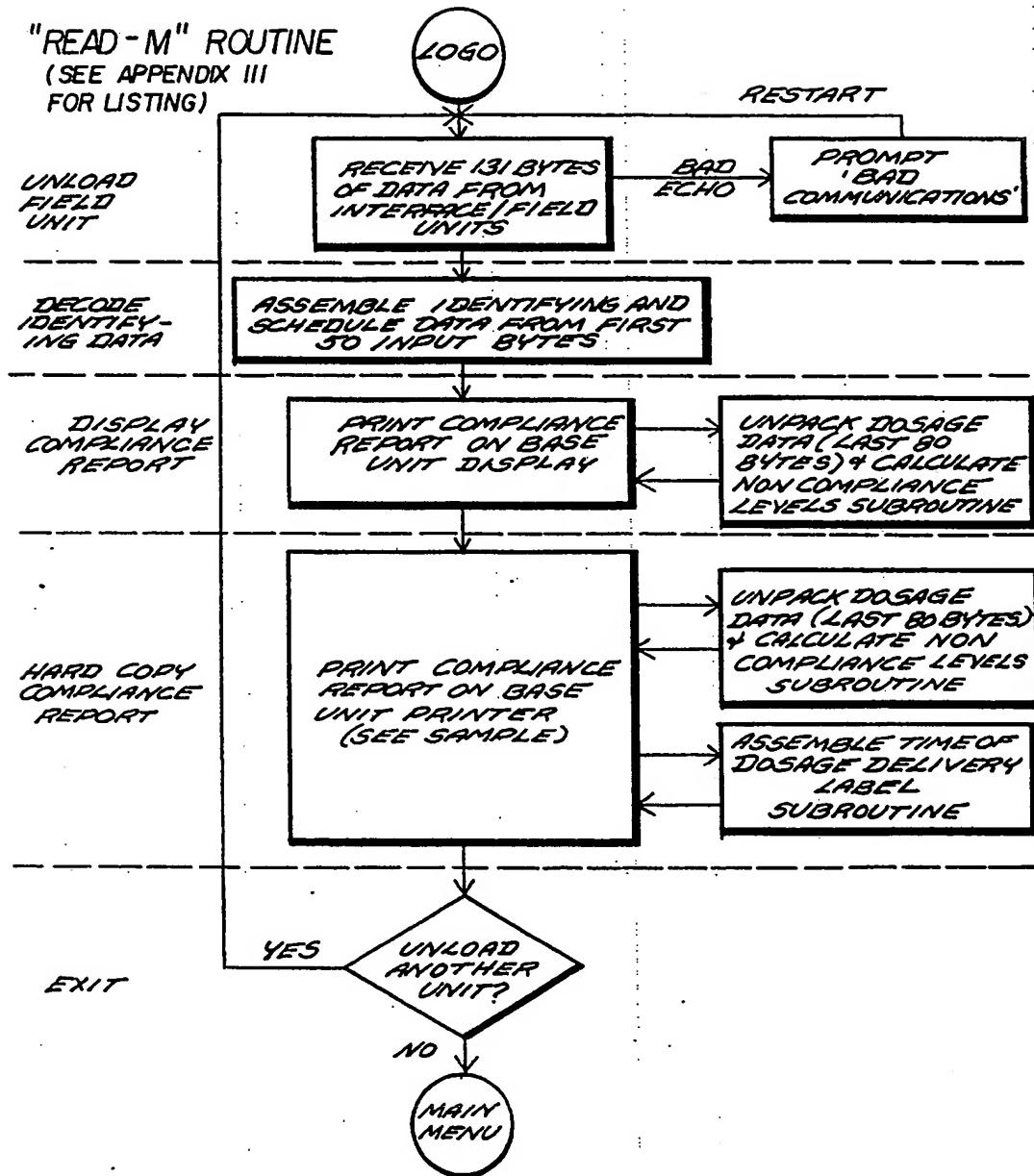


FIG. 30

# INTERNATIONAL SEARCH REPORT

International Application No **PCT/US86/00711**

## **I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all)**

According to International Patent Classification (IPC) or to both National Classification and IPC  
**Int. Cl.4 B65D 83/04**  
**U.S. Cl. 221/3**

## **II. FIELDS SEARCHED**

Classification System	Minimum Documentation Searched <sup>1</sup>		Classification Symbols
	186/55	206/531, 532, 534	
	221/3, 5, 9, 13, 15, 25, 30-31, 71-74, 265-266		
	340/309.3, 309.4, 309.15	364/479	

Documentation Searched other than Minimum Documentation  
to the Extent that such Documents are Included in the Fields Searched <sup>2</sup>

## **III. DOCUMENTS CONSIDERED TO BE RELEVANT <sup>14</sup>**

Category <sup>15</sup>	Citation of Document, <sup>16</sup> with indication, where appropriate, of the relevant passages <sup>17</sup>	Relevant to Claim No. <sup>18</sup>
Y	US, A, 3,917,045, (Williams), 04 November 1975.	1-5, 9-20, 26-49, 84-89, 92-96, 98.
Y, P	US, A, 4,572,403, (Benaroya), 25 February 1986.	10-20, 26- 49, 55-82, 84-89, 92- 96, 98
Y	US, A, 2,941,643, (Donnelly), 21 June 1960.	1-5, 9, 17- 20, 35, 46- 49, 66, 73, 98
Y	US, A, 3,984,030, (Morini), 05 October 1976.	31, 60
Y	US, A, 3,985,264, (Shaw), 12 October 1976.	32-33, 61- 63, 73-82, 86-89, 92- 93, 95-96

<sup>14</sup> Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance  
 "E" earlier document but published on or after the International filing date  
 "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)  
 "O" document referring to an oral disclosure, use, exhibition or other means  
 "P" document published prior to the International filing date but later than the priority date claimed

"T" later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"A" document member of the same patent family

## **IV. CERTIFICATION**

Date of the Actual Completion of the International Search <sup>19</sup>

**26 June 1986**

International Searching Authority <sup>20</sup>

**ISA/US**

Date of Mailing of this International Search Report <sup>21</sup>

**02 JUL 1986**

Signature of Authorized Officer <sup>22</sup>

*Michael S. Huppert* 6-30-86  
**Michael S. Huppert**

## III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category <sup>a</sup>	Citation of Document, <sup>10</sup> with indication, where appropriate, of the relevant passages <sup>11</sup>	Relevant to Claim No <sup>12</sup>
Y	US, A, 1,845,879, (Knee), 16, February 1932	40, 70
Y	US, A, 3,815,780, (Bauer), 11 June 1974	94
A,	US, A, 772,503, (Dodson), 18 October 1904	
A	US, A, 3,369,697, (Glucksman) 20, February 1968	
A	US, A, 3,968,900, (Stambuk), 13 July 1976	

## FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V.  OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE 10

This International search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1.  Claim numbers \_\_\_\_\_, because they relate to subject matter<sup>12</sup> not required to be searched by this Authority, namely:

2.  Claim numbers \_\_\_\_\_, because they relate to parts of the International application that do not comply with the prescribed requirements to such an extent that no meaningful International search can be carried out<sup>13</sup>, specifically:

VI.  OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING 11

This International Searching Authority found multiple inventions in this International application as follows:

The lack of unity of invention holding, set forth on PCT/ISA/206 is hereby withdrawn.

1.  As all required additional search fees were timely paid by the applicant, this International search report covers all searchable claims of the International application.
2.  As only some of the required additional search fees were timely paid by the applicant, this International search report covers only those claims of the International application for which fees were paid, specifically claims:
3.  No required additional search fees were timely paid by the applicant. Consequently, this International search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:
4.  As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

## Remark on Protest

The additional search fees were accompanied by applicant's protest.  
 No protest accompanied the payment of additional search fees.